IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

MSP RECOVERY CLAIMS, SERIES, LLC, a Delaware entity, MAO-MSO RECOVERY, LLC, a Delaware entity, MSPA CLAIMS 1, LLC, a Florida entity, MAO-MSO RECOVERY II, LLC, a Delaware entity,	§	Case No.
Plaintiffs,	§	DEMAND FOR JURY TRIAL
v.	§	
	§	CLASS ACTION COMPLAINT
CVS HEALTH CORPORATION, CAREMARK RX, L.L.C., EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS, INC., SANOFI-AVENTIS U.S. LLC, NOVA NORDISK INC., and ELI LILLY AND COMPANY,	§	
Defendants.	§	

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COMPLAINT

Plaintiffs, MSP RECOVERY CLAIMS, SERIES LLC, a Delaware entity, MSPA Claims 1, LLC, a Florida entity, MAO-MSO Recovery, LLC, a Delaware entity, and MAO-MSO Recovery II, LLC, a Delaware entity (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, bring this action against Defendants CVS Health Corporation ("CVS Health"), Caremark Rx, L.L.C., Express Scripts Holding Company, Express Scripts, Inc. ("Express Scripts"), Novo Nordisk Inc. ("Novo Nordisk"), Eli Lilly and Company ("Eli Lilly"), and Sanofi-Aventis U.S. LLC ("Sanofi") (collectively, "Defendants") to redress Plaintiffs' injuries due to Defendants' insulin pricing scheme, which has driven up the cost of insulin to the substantial benefit of the Defendants. Plaintiffs' allegations, proof and statistical data presented in this complaint are based on their own experiences and personal knowledge, their research, the research of their counsel, publicly available articles, studies, reports, and other sources.

INTRODUCTION

1. Diabetes is an epidemic in the United States. One in five health care dollars is spent caring for people with the condition. In total, nearly 30 million people, 9.3% of the country, live with diabetes. Of this number, approximately six million people rely on daily insulin treatments to survive. Interruptions to or interference with insulin therapy (e.g., insufficient insulin) can have severe consequences, including sustained damage to the kidneys, heart, nerves, eyes, feet, and skin. Indeed, diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States. Missed or inadequate insulin therapy can leave people with diabetes with too little insulin in their system, triggering hyperglycemia (hyperosmolar hyperglycemic state or "HHS") and then diabetic ketoacidosis ("DKA"). Left untreated, DKA can lead to loss of consciousness and death within days. DKA is responsible for more than 500,000

hospital days per year at an estimated annual direct medical expense and indirect cost of $2.4 billion.

2. Defendants Sanofi, Novo Nordisk, and Eli Lilly (collectively, the "Drug Manufacturer Defendants") manufacture analog insulin currently used to treat diabetes in the United States and its territories—the relevant geographic market. Over the course of the last decade, each has raised the list prices of their respective analog insulin—i.e., those insulin necessary to maintain the current standard of care—in an astounding and inexplicable manner. Drugs that used to cost $25 per prescription now cost between $250 and $450. And in the last five years alone, the Drug Manufacturer Defendants have raised their list prices for analog insulin by over 150%.

3. That insulin cost is in addition to the hundreds of dollars that people living with diabetes must spend on their other diabetes supplies (e.g., the test strips and glucose meter that people with diabetes must use to read their blood sugar levels prior to taking insulin and the syringes, along with pen needles, infusion sets, and/or pods they need to administer their insulin).

4. The Drug Manufacturer Defendants' analog insulin price increases have been both rapid and in lock-step.

5. The skyrocketing cost of insulin cannot be explained away with typical drug company rationalizations for high costs. Indeed, the manufacturers *admit* that their price hikes are unrelated to any jump in production or research and development costs. Instead, the increased list prices are the result of a scheme and enterprise among the Drug Manufacturer Defendants, and the three largest Pharmacy Benefit Managers ("PBM(s)"), CVS Health, and Express Scripts (collectively the "PBM Defendants"). In this scheme, the Drug Manufacturer Defendants set two different prices for their insulin treatments: a publicly-available "list" price, and an undisclosed

lower, "net" price that the PBMs pay for the drugs (the "Insulin Pricing Scheme"). For the analog insulin, the gap between these two figures has significantly increased.

6. To understand the Insulin Pricing Scheme at the core of this case, and the reason it is so profitable for the Defendants, it is first necessary to understand the role of PBMs in the pharmaceutical supply chain in the United States. The PBM Defendants serve as both middlemen and gatekeepers between drug manufacturers on the one hand, and health insurers and patients on the other. Business is booming for the PBM Defendants. Together, they report more than $200 billion a year in revenue. And they control over 80% of the PBM industry, administering and managing pharmacy benefits for over 180 million insured people.

7. Based purportedly on the price they secure, the PBM Defendants set up *exclusionary* tiered formularies for their clients (in this case MAOs). Formularies are ranked lists of drugs, where some cheaper and some more effective medicines are supposed to be placed into lower tiers. The MAOs rely on these formularies to determine how much of their beneficiaries drug costs they will cover. Drugs in lower, preferred formulary tiers are supposed to be cheaper for beneficiaries.

8. Where two medicines are largely interchangeable, a PBM will *sometimes* exclude the more expensive of the two from its formulary—again, purportedly based on the price of the drug for its customers. When a drug is excluded from or disfavored from the formulary, MAOs using that formulary either will not reimburse their beneficiaries for purchase of that drug or will require the beneficiary to pay a larger coinsurance amount calculated based on the list price rather than the actual price paid by the PBM. As a result, exclusionary formularies enable PBMs, including the PBM Defendants here, to push patients toward certain brands of drugs over others. This power gives them enormous control over drug purchasing behavior and leverage over

manufacturers.

9. Whereas the PBM Defendants could use their market power as gatekeepers to drive down drug prices for patients, by forcing drug companies to compete on price for formulary placement, instead, they and the Drug Manufacturer Defendants have figured out a way to game the system for their mutual benefit. To gain formulary access, the Drug Manufacturer Defendants *raise* their published list prices, and then "rebate" a significant portion of the list price back to the PBM Defendants. These rebates amount to nothing more than a remuneration, or kickback to the PBM Defendants. The rebates are provided under a variety of labels—discounts, credits, concession fees, etc. Regardless of their label, these rebates are a *quid pro quo* for formulary inclusion or placement.

10. In the context of this complaint, rebates shall include all payments or financial benefits of any kind conferred by the Manufacturers to the PBMs, either directly via contract, or indirectly via Manufacturer-controlled intermediaries.

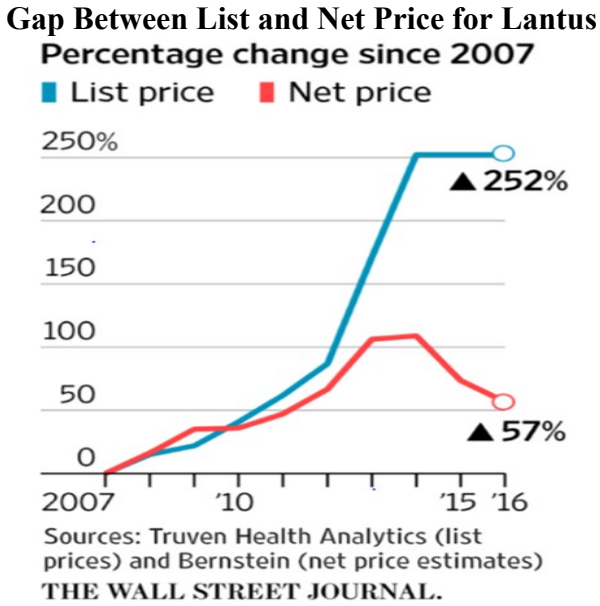
11. The result of this rebating scheme is a wide difference between the list price used by the Drug Manufacturer Defendants, and the net price realized by the Manufacturers once all rebates paid to the PBMs are considered. This difference may be as great as, or even greater than, 50% of the list price.

12. The PBM Defendants pass a portion of rebates on to their major insurer clients (some of which are owned by or affiliated with them), and pocket the rest. The higher the rebate, the more the PBM Defendants pocket. The total amount and nature of the rebates, the amount the PBM pockets, and the amount the PBM passes through to clients/payers are all carefully guarded secrets.

13. This rebate scheme creates a best of both worlds scenario for the Defendants. The

PBM Defendants obtain ever larger rebates in exchange for access to the exclusionary formularies, increasing their take, and the Drug Manufacturer Defendants pay the rebates without cutting into their profit margins. This is because the net price for their drugs—the amount the PBM Defendants pay—stays the same. In effect, the *quid pro quo* arrangement between the PBMs and Drug Manufacturers creates a price war in reverse. The Drug Manufacturer Defendants keep raising their list prices, so that they can pay larger and larger kickbacks to the PBM Defendants so their drugs will be featured on the formulary.

14. The result of the scheme is an ever-widening gap between the price paid by the PBM Defendants for insulin (i.e., the net-realized price received by Manufacturer Defendants), and the publicly available Manufacturer list price. The following chart shows this gap for Lantus, Sanofi's top-selling insulin:



15. The PBM Defendants tout their market power to sign clients, claiming superior ability to drive down drug prices. They boast about the "rebates" or "discounts" for which they bargain with drug manufacturers. The story they tell is that these rebates and discounts are obtained for the benefit of patients since they purportedly result in lower costs for prescription drugs.

16. But the story the PBM Defendants tell is far from the whole truth. They obtain rebates and discounts, but neglect to reveal the large portion of the rebates that they pocket as a kickback for formulary access. They also neglect to reveal that their formulary decisions are based on the amount of the spread they obtain from the rebate paid by drug companies. Resulting in higher drug costs for MAOs, who pay based off of the list price, not the lower price paid by the PBMs once all rebates and other financial benefits received by the PBM from the Manufacturers. Indeed, the PBM Defendant misrepresents the role they play in the supply chain, and their impact on the prices MAOs pay for drugs.

17. The PBMs are avaricious middlemen, with a stranglehold on the prescription drug supply chain. Their scheme to sell formulary access for rebates, is nothing more than a remuneration, or kickback, that drives up the cost of prescription drugs resulting in higher operating costs for MAOs and thus, depleting the Medicare Trust Fund quicker.

18. The Drug Manufacturer Defendants are equally at fault. Their conduct deprives MAOs of a fair price for insulin—a price that would result from the operation of normal market forces. They bargain for market share by providing ever-larger kickbacks, to PBMs and entering into exclusive relationships with those PBMs (e.g., Eli Lilly and Express Scripts, Novo Nordisk and CVS Caremark). Thus, inflating the prices paid by MAOs to preserve their net-realized price. Their refusal to disclose their net-realized prices for insulin and the web of confidentiality agreements have been critical to the furtherance of the Insulin Pricing Scheme.

19. Eli Lilly spokeswoman, Julie Williams, admitted the company's pricing scheme in a statement issued in January 2017:

> There is a wide and growing discrepancy between the published "list price" Lilly sets and the "net price" that Lilly actually receives.
>
> The list price (also known as the wholesale acquisition cost or WAC) is the price

> that a manufacturer sets as a starting point for negotiations with federal and state governments, private insurers, and pharmacy benefit managers to gain formulary access. Manufacturers also use list price in negotiations with wholesalers and others involved in the distribution process.
>
> The amount the manufacturer receives after all discounts and rebates are applied is considerably less than the list price. For example, the net price for Humalog—our most commonly used insulin—increased by 4 percent over the five-year period of 2009 to 2014, which is a much smaller increase than what some consumers have experienced.

20. While this admission is illuminating, it far from solves the problem of opacity in drug pricing and kickback schemes. This New York Times op-ed called for transparency in setting prices:

> In the meantime, we need a fair and transparent system for setting prices. In much of Europe, insulin costs about a sixth of what it does here. That's because the governments play the role of pharmacy benefit managers. They negotiate with the manufacturer directly and have been very effective at driving down prices. In the United States, we rely on the private sector and a free market for drug pricing. But in order for this to work, we need to regulate it better and demand greater transparency.

Kasia Lipska, Break Up the Insulin Racket, N.Y. Times (Feb. 20, 2016), https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html.

21. Medicare Advantage Organizations ("MAOs") are victims of this pricing scheme by being forced to pay higher prices for insulin provided to beneficiaries. MAOs are forced to pay the expenses for insulin because their payment obligations are based on the list prices, not the opaque net prices provided to the PBM Defendants. The more MAOs spend on supra-competitive pharmaceuticals the less MAOs can spend on other care and benefits for their beneficiaries. Further, Part D beneficiaries are vulnerable to the Medicare Part D "Donut Hole," at an expedited pace.

22. This action and lawsuit affirmatively alleges that the two largest PBMs—CVS Health, and Express Scripts,—violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961 *et seq.*, and state common law, by engaging in: extortion; a RICO

enterprise; wire fraud; and anticompetitive and deceptive conduct, for the purpose of unlawfully extracting larger rebates along with other payments, i.e., "PBM kickbacks", from the Drug Manufacturer Defendants. Plaintiffs further alleges that the Drug Manufacturer Defendants, while angling to secure, via exclusionary formulary placement, have provided the PBM Defendants kickbacks. The Drug Manufacturer Defendants provided these kickbacks by inflating the list prices of rapid and long-acting analog insulin drugs, and further conspiring with the PBM Defendants to prevent disclosure of net prices to the thousands of individual consumers represented in this action by Plaintiffs. Defendants' Insulin Pricing Scheme directly and foreseeably causes MAOs to overpay for these life-saving medications. Thus, this collective action is brought to redress Plaintiffs' injuries that flow from Defendants' Insulin Pricing Scheme—which has driven up the cost of insulin to the substantial benefit of PBMs and insulin manufacturers—and to obtain prospective injunctive relief to curtail Defendants' practices and provide greater transparency in insulin pricing, as well as lower prices going forward. The causes of action asserted herein allow, *inter alia*, the remedies of monetary damages, damage multipliers, surcharge, restitution, injunctive relief, and other equitable relief.

23. This lawsuit seeks reimbursement for those insulin expenses paid for by the Plaintiffs' assignors[15], paid on behalf of thousands of individual beneficiaries scattered around Texas and all the other states of the United States which claims have been contractually assigned to Plaintiffs for any and all recovery, as well as other MAOs across the nation, or its assignees that should not have been forced to pay supra-competitive prices for their beneficiaries.

PARTIES

[15] Plaintiffs assert the rights of MAOs via contractual assignment of all rights, title, and interest allowing them to bring these claims.

24. MSP Recovery Claims, Series LLC, is a Delaware entity with its principal place of business located at 5000 S.W. 75th Avenue, Suite 400, Miami, FL 33155. Numerous MAOs across the United States have assigned their rights to MSP Recovery Claims, Series LLC, to recover payments for fraudulently-inflated prescriptions. As a result of these assignments, MSP Recovery Claims, Series LLC, is empowered and has standing herein to pursue the claims of its Assignors that purchased Insulin at supra-competitive prices as a result of the Defendants' pattern of racketeering activity and anti-competitive conduct. Accordingly, Plaintiffs, MSP Recovery Claims, Series LLC, by assignment, has suffered damages and now seeks reimbursement for the money lost by these MAOs that were forced to pay inflated prices for Insulin.

25. Plaintiffs MSPA Claims 1, LLC is a Florida entity, with its principal place of business located at 2600 S. Douglas Rd., Suite 1008, Coral Gables, FL 33134. MSPA Claims 1 is a citizen of the State of Florida and is not a citizen of the state of any of the Defendants. Numerous MAOs across the United States have assigned their rights to MSPA Claims 1, LLC, to recover payments for fraudulently-inflated prescriptions. As a result of these assignments, MSPA Claims 1, LLC, is empowered and has standing herein to pursue the claims of its Assignors that purchased Insulin at supra-competitive prices as a result of the Defendants' pattern of racketeering activity and anti-competitive conduct. Accordingly, Plaintiffs, MSPA Claims 1, LLC, by assignment, has suffered damages and now seeks reimbursement for the money lost by these MAOs that were forced to pay inflated prices for Insulin.

26. Plaintiffs, MAO-MSO Recovery, LLC, is a Delaware entity with its principal place of business at 5000 S.W. 75th Avenue, Miami, FL 33155. Numerous MAOs across the United States have assigned their rights to MAO-MSO Recovery, LLC, to recover payments for fraudulently-inflated prescriptions. As a result of these assignments, MAO-MSO Recovery, LLC,

is empowered and has standing herein to pursue the claims of its Assignors that purchased Insulin at supra-competitive prices as a result of the Defendants' pattern of racketeering activity and anti-competitive conduct. Accordingly, Plaintiffs, MAO-MSO Recovery, LLC, by assignment, has suffered damages and now seeks reimbursement for the money lost by these MAOs that were forced to pay inflated prices for Insulin.

27. Plaintiffs, MAO-MSO Recovery II, LLC, is a Delaware entity with its principal place of business at 45 Legion Drive, Cresskill, NJ 07626. Numerous MAOs across the United States have assigned their rights to MAO-MSO Recovery II, LLC, to recover payments for fraudulently-inflated prescriptions. As a result of these assignments, MAO-MSO Recovery II, LLC, is empowered and has standing herein to pursue the claims of its Assignors that purchased Insulin at supra-competitive prices as a result of the Defendants' pattern of racketeering activity and anti-competitive conduct. Accordingly, Plaintiffs, MAO-MSO Recovery II, LLC, by assignment, has suffered damages and now seeks reimbursement for the money lost by these MAOs that were forced to pay inflated prices for Insulin.

28. Plaintiffs and the putative class members ("Class Members") paid Medicare benefits on behalf of the Medicare-eligible beneficiaries enrolled under the Medicare Advantage ("MA") program. MAOs and/or their Assignees paid or otherwise incurred losses for insulin through Defendants' racketeering and unlawful practice(s).

29. Defendant CVS Health Corporation is a corporation organized under the laws of Delaware and headquartered at One CVS Drive, Woonsocket, Rhode Island, 02895. CVS Health is a PBM and, as such, contracts on behalf of health plans and insurers with Novo Nordisk, Eli Lilly, and Sanofi for the purchase of the analog insulin medications that these pharmaceutical companies make. CVS Health Corporation provides comprehensive prescription benefit

management services to over 2,000 health plans, including corporations, managed care organizations, insurance companies, unions and government entities, and covers 65 million lives. Defendant CVS Health Corporation can be served at 1 CVS Drive, Woonsocket, RI 02895-6146.

30. Defendant Caremark Rx, L.L.C. is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management subsidiaries. Caremark Rx, L.L.C. is a subsidiary of Defendant CVS Health Corporation. Defendant Caremark Rx, L.L.C. can be served at 1 CVS Drive, Woonsocket, RI 02895-6146.

31. Defendant Caremark Rx, Inc. is a corporation organized under the laws of Delaware and headquartered at 211 Commerce Street, Suite 800, Nashville, Tennessee, 37201. Caremark Rx, Inc. is an immediate or indirect parent of many subsidiaries, including pharmacy benefit management subsidiaries, and a subsidiary of Defendant CVS Health Corporation. Collectively, Defendant CVS Health Corporation, Defendant Caremark Rx, L.L.C. and Defendant Caremark Rx, Inc. are referred to as "CVS Health." Defendant Caremark Rx, Inc. can be served at 1 CVS Drive, Woonsocket, Rhode Island 02895-6146.

32. Defendant Express Scripts Holding Company is a Delaware corporation. Its principal place of business is at 1 Express Way, St. Louis, Missouri, 63121. Defendant Express Scripts Holding Company can be served at 1 Express Way, Saint Louis, MO 63121-1824.

33. Defendant Express Scripts, Inc. is a corporation organized under the laws of Delaware and headquartered at 1 Express Way, St. Louis, Missouri, 63121. Express Scripts is a pharmacy benefit manager and, as such, contracts on behalf of health plans and insurers with Novo Nordisk, Eli Lilly, and Sanofi for purchase of the analog insulin medications these pharmaceutical companies make. As the largest pharmacy benefit management organization in the United States, Defendant Express Scripts Inc. covers 79 million lives. Defendant Express Scripts, Inc. is a

subsidiary of Defendant Express Scripts Holding Company. Defendant Express Scripts, Inc., and Defendant Express Scripts Holding Company collectively are referred to as "Express Scripts." Defendant Express Scripts, Inc. can be served through Corporation Service Company d/b/a CSC - Lawyers Inc., 211 E. 7th Street, Suite 620, Austin, Texas 78701, their authorized agent for service of process in the State of Texas.

36. Together, CVS Health, and Express Scripts are referred to herein as the "PBM Defendants."

34. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability company with its headquarters in Bridgewater, New Jersey. Sanofi manufactures Apidra, a rapid-acting insulin, and Lantus, a long-acting insulin. For 2015, the Sanofi group reported that Lantus "was the Group's leading product … representing 17.2% of the Group's aggregate net sales for the year." Defendant Sanofi-Aventis U.S. LLC can be served through Corporation Service Company d/b/a CSC -Lawyers Inc., 211 E. 7th Street, Suite 620, Austin, Texas 78701, their authorized agent for service of process in the State of Texas.

35. Defendant Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation. Its headquarters are in Plainsboro, New Jersey. Novo Nordisk manufactures insulin products including NovoLog, a rapid-acting insulin, and Levemir, a long-acting insulin. Defendant Novo Nordisk Inc. can be served at 800 Scudders Mill Road, Plainsboro, NJ 08536.

36. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation, and its principal place of business is in Indianapolis, Indiana. Eli Lilly produces the rapid-acting insulin product Humalog. Defendant Eli Lilly and Company can be served through National Registered Agents, Inc., 1999 Bryan St., Suite 900, Dallas, Texas 75201, their authorized agent for service of process in the State of Texas.

Standing

37. Plaintiffs has been assigned all legal rights of recovery and reimbursement for health care services and Medicare benefits provided by MAOs that administer Medicare benefits for Medicare beneficiaries under Medicare Part C and/or Medicare Part D; whether said rights arise from (i) contractual agreements, such as participation and network agreements with capitation and risk sharing arrangements, and/or (ii) state and federal laws that provide for the reimbursement of payments made by the assignor health plans, including the right to recover claims for health care services on a fee-for-service basis.

38. At all material times hereto, one of Plaintiffs' assignors[26] provided Medicare benefits to Enrollee S.E., including payment for Enrollee's insulin prescription.[27] S.E. purchased the insulin at a Walmart store in Converse, Texas. Plaintiffs represents the individual interests of thousands of beneficiaries whose claims have been assigned to Plaintiffs that are similarly situated to S.E.

39. Plaintiffs provided payment for Enrollee's insulin prescription distributed in Bexar County, Texas.

40. The agreement between Plaintiffs and Plaintiffs' Assignor contains the following assignment language:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery any and all of Client's right, title, ownership and interest in and to all claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the claims and all rights and claims against primary payers and/or third parties that

[26] A full list of Plaintiffs' Assignors will be provided to Defendants' upon their execution of a Protective Order
[27] In order to ensure that this document is HIPAA compliant, Plaintiffs' enrollee, S.E., shall only be referred to as "Enrollee." The full name of Enrollee will be provided to Defendants upon the execution of a Protective Order.

may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws.

JURISDICTION AND VENUE

41. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 as Plaintiffs' claims arise under federal law, and under 18 U.S.C. § 1964(c) as this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court also has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

42. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including Bexar County, Texas located in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district. 15 U.S.C. § 22 provides for nationwide service of process. This Court also has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in Texas.

43. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in Bexar County, Western District of Texas, and because some of the actions giving rise to the complaint took place within this district. Venue is also proper in this District pursuant to 29 U.S.C. § 1132(e)(2), because Defendants reside or may be found in this District and some or all of the fiduciary breaches or other violations for which relief is sought occurred in or originated in this District. Venue is also proper in this District pursuant to 18 U.S.C. § 1965, because most Defendants reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any

Defendant residing elsewhere be brought before this Court. Venue is also proper in this District pursuant to 15 U.S.C. § 22 because most Defendants inhabit, are found, have an agent, or transact business in this District.

FACTUAL ALLEGATIONS

Life Saving Insulin is Not a New Drug.

Diabetes Requires Insulin.

50. Diabetes is a condition in which the body does not properly process food for use as energy. In a non-diabetic person, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to glucose, or sugar, in the bloodstream to be effectively used, by the body, as energy. People with diabetes are unable to make enough insulin or cannot use insulin as effectively as necessary, causing glucose, or sugar, to build up in the blood-stream. These consistently high levels of blood glucose, or blood sugar, pose several serious health risks including heart disease, blindness, kidney failure, and lower-extremity amputations. Though treatable, diabetes can be fatal or severely debilitating if left untreated.

51. As of 2014, 29.1 million people in the United States, or 9.3 percent of the population, had diabetes and that number continues to grow. The most common types of diabetes in the U.S. are type 1 and type 2, as well as gestational diabetes. Type 1 diabetics are unable to produce insulin at all; as their immune system attacks and destroys the cells in the pancreas that make it. With type 2 diabetes, although people with the condition can produce insulin, they are unable to use it effectively, and about 95 percent of cases of diabetes in adults are type 2. Regular use of prescription insulin is necessary to treat type 1 and type 2 diabetes to prevent life-threatening health complications.

Types of Insulin

52. In 1982, synthetic insulin, or "human insulin," was developed and marketed by Eli Lilly and other manufacturers. This type of insulin was marketed as Humulin R (rapid) and N (NPH, intermediate-acting).

53. Subsequently, doctors found that each diabetes patient may react differently to each formulation of the protein. This recognition gave rise to the most recent iteration of insulin available on the market today: "analog insulin."

Analog Insulin

54. Analog insulin is a genetically modified form of insulin whereby the amino acid sequence is altered to change how the insulin is absorbed, distributed, metabolized and excreted.

55. Analog insulin's are closely related to the human insulin structure, and were developed for specific aspects of glycemic control in terms of fast action (prandial insulin) and long action (basal insulin's). The first biosynthetic insulin analog was developed by Eli Lilly and Company for clinical use at mealtime, with the brand name Humalog. It is more rapidly absorbed after subcutaneous injection than regular insulin, with an effect 15 minutes after injection. Other rapid-acting analogs are Novolog and Apidra, with similar profiles. These are used in combination with longer-acting insulins Lantus and Levemir. These rapid-acting and long-acting analog insulin's were introduced in the U.S. between 1996 and 2006. They replaced older insulins, such as NPH, that had been developed during the 1940s, and regular (*e.g.* Lente, Humulin), developed in the 1970s and marketed in early 1980s.

56. Modern forms of insulin[i], such as Humalog, which is short acting, and Lantus, a long-acting insulin, can help diabetics maintain blood sugar levels and improve their quality of life. Indeed, some researchers believe that human insulin has become obsolete in private clinical practice. Nevertheless, some doctors are again beginning to recommend its use despite its

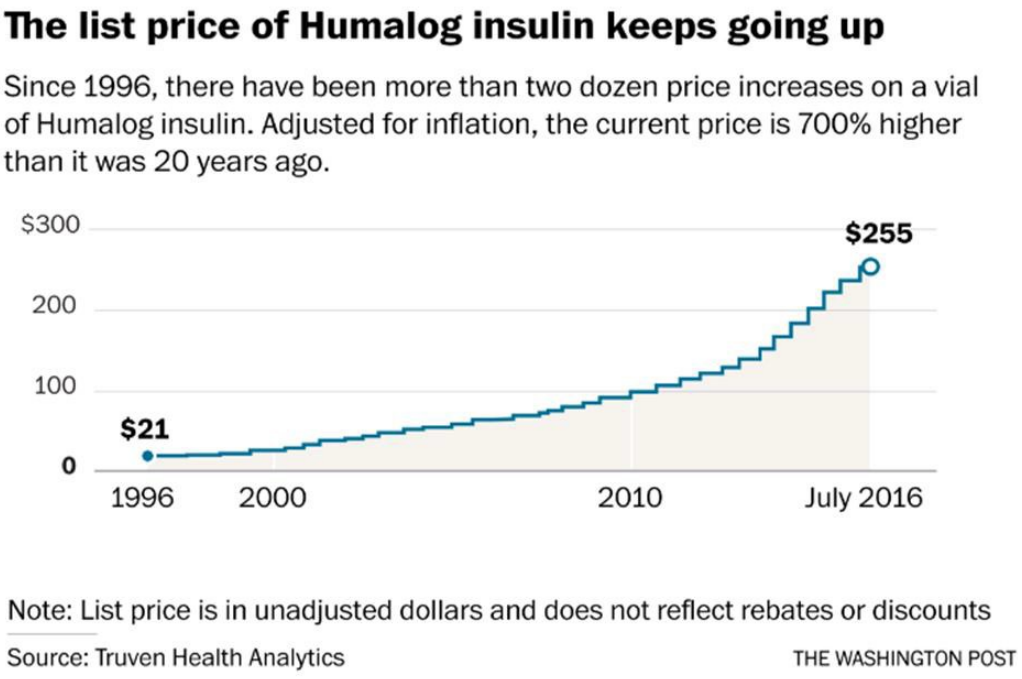
downsides for patient health and effective diabetes management, because it can be obtained at much cheaper prices than more effective analog insulin, at least for now. In a stark reversal of decades of progress toward more effective diabetes management regimens, the American Diabetes Association and the Endocrine Society recently called for a return to obsolete insulin regimens for some patients, to solve the alleged pricing crisis engineered by Defendants.

57. As for the lion's share of today's insulin market—analogs—most of these insulins have been available for 15-20 years, yet as explained next, their prices have gone through the roof.

Insulin's Price Has Risen Dramatically in the Past Decade.

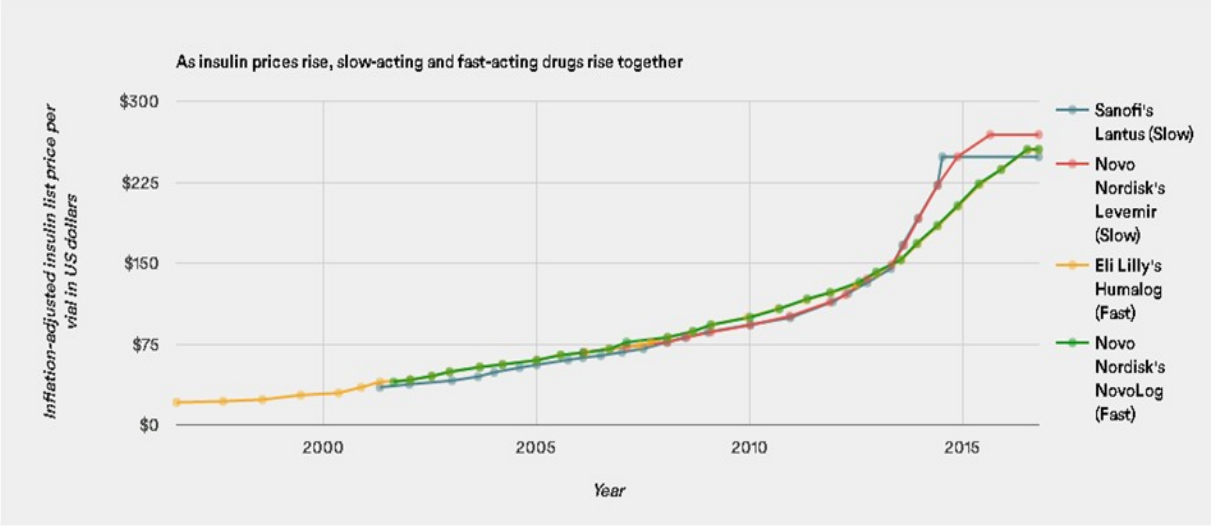
58. Since 2003, the cost of one vial of insulin or one box of five insulin pens has increased by more than 500%; an astounding increase especially when compared to a general inflation rate of 8.3% and a medical inflation rate of 46% in this same time period.

59. These price increases have occurred even in the face of supposed competition between manufacturers making similar drugs. Since the mid-1990s, there have been more than two dozen price increases on a vial of Humalog insulin, as detailed below:



60. Driven by these price hikes, more money is spent per patient on insulin than all other diabetes medications combined.

61. The overlap in price hikes across both categories of analog insulins (rapid and long-acting) is remarkable as well:

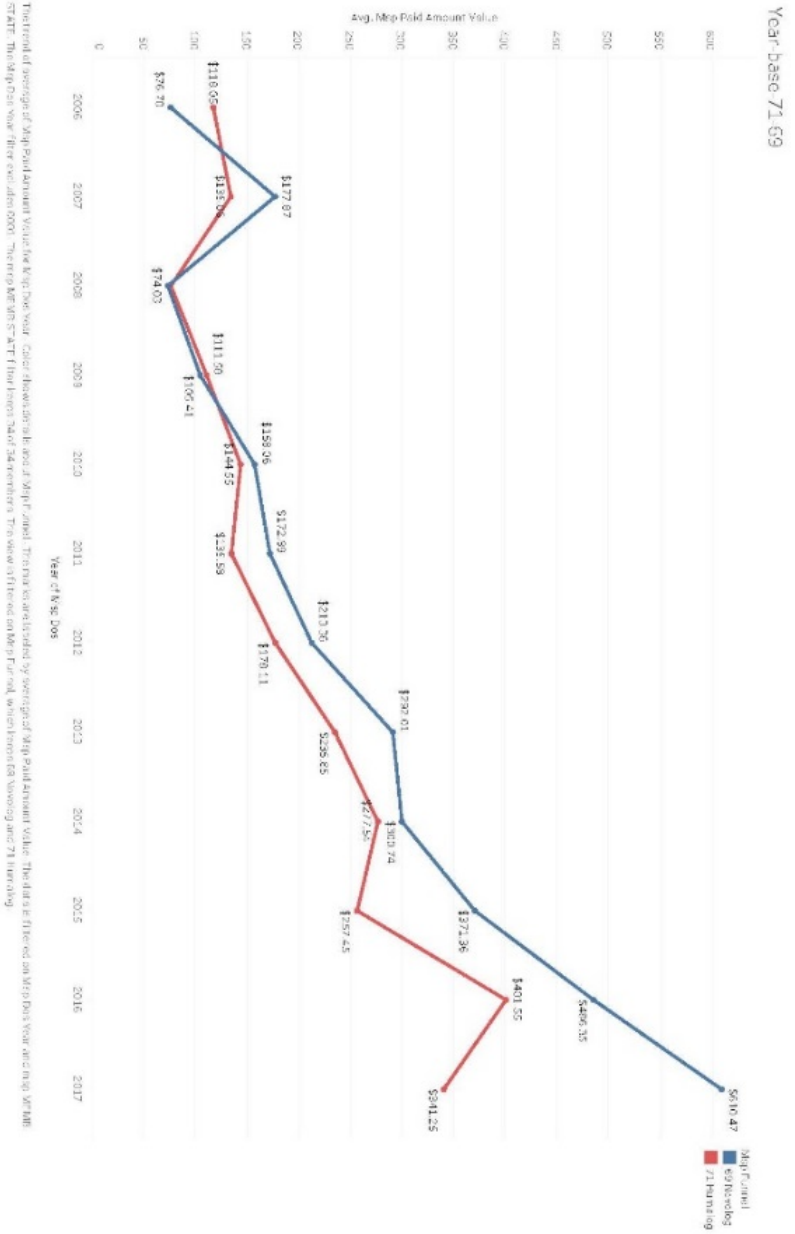


JEFFERY DELVISCIO/STAT
Source: Truven Health Analytics

62. Moreover, while lower-cost generic forms of many drugs are available to purchase in the United States there is no generic form of insulin. Insulin was first extracted nearly 100 years ago, only three major pharmaceutical companies hold patents in the United States allowing them to manufacture insulin. If practitioners prescribe cheaper versions of insulin that still are available in the United States, the prescriptions instead are filled with newer recombinant products. Thus, nearly a century after its discovery, there is still no inexpensive supply of insulin for people living with diabetes in the United States. Instead, third-party payers who provide medical treatments and supplies to beneficiaries who need insulin to survive are stuck in Defendants' Pricing Scheme.

63. Below are graphical representations of Plaintiffs' yearly average paid per insulin prescription.[60]

[60] The graphs are based on assigned claims data compiled by Plaintiffs.


Year base 71.69
Avg. Mkp Paid Amount Value
Year of Svc Dos
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2007
2008
2009
2010
2011
2012
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2014
2015
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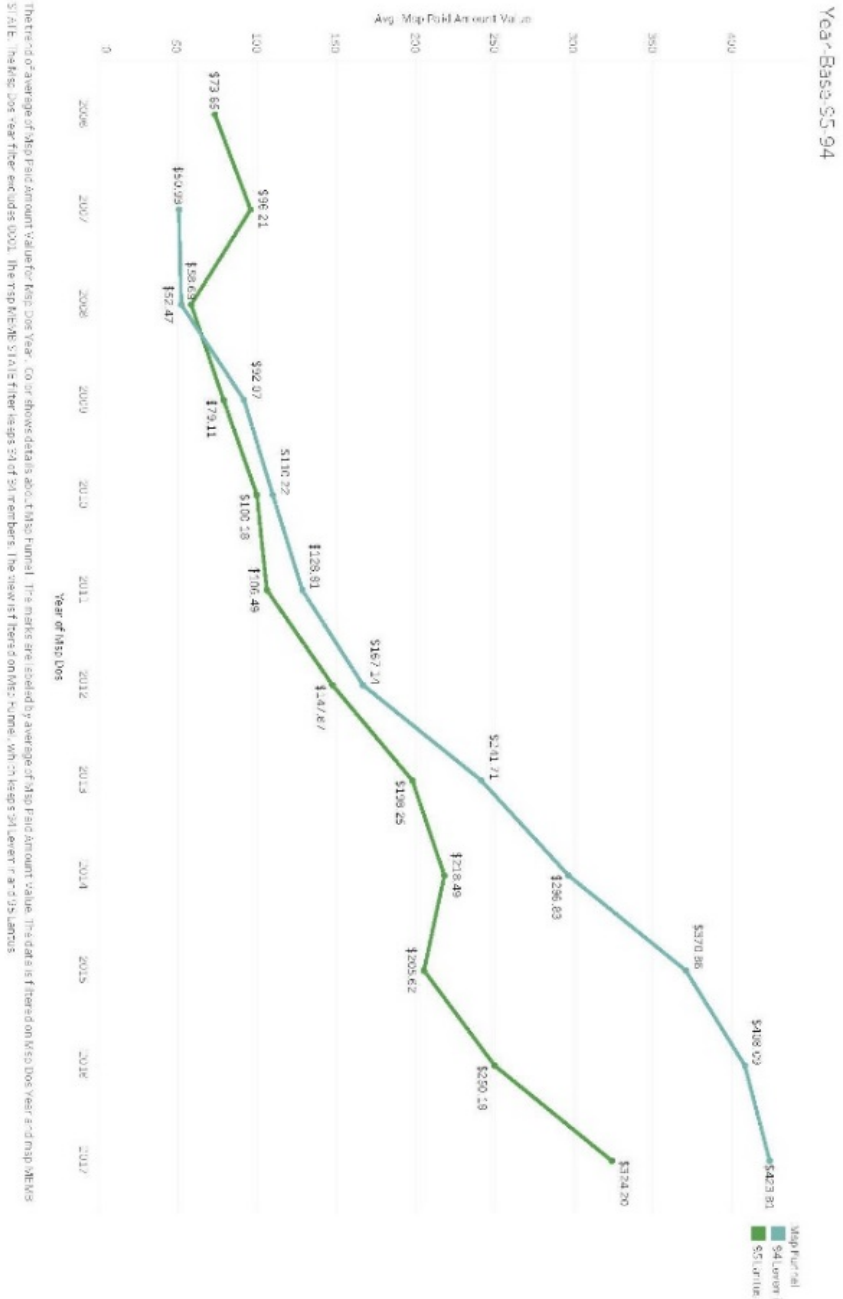
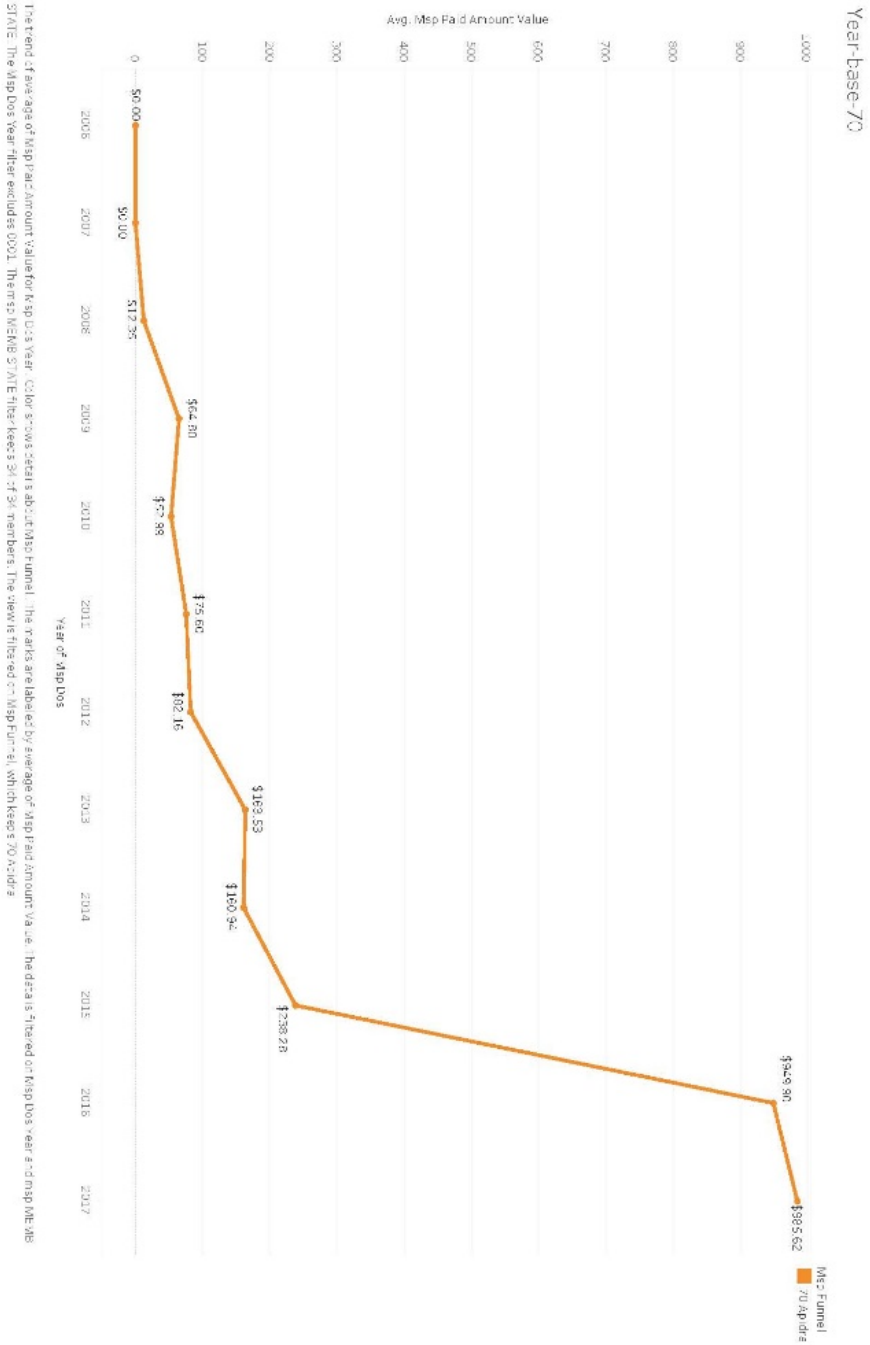
$74.03
$111.00
$159.06
$172.99
$213.36
$230.01
$303.74
$372.36
$406.35
$610.47
$76.70
$110.05
$144.55
$135.59
$170.11
$236.85
$277.55
$257.45
$401.55
$241.25


Year Base 95 94
Avg. Msp Paid Amount Value
Year of Msp Dos
$73.65
$96.21
$59.93
$58.63
$52.47
$92.07
$79.11
$130.22
$100.18
$128.91
$106.49
$167.20
$141.71
$198.25
$218.49
$205.62
$296.83
$250.19
$370.86
$308.02
$423.81
$374.20


Year-base-70
Avg. Msp Paid Amount Value
0
100
200
300
400
500
600
700
800
900
1000
$0.00
$0.00
$12.35
$64.80
$75.60
$102.16
$169.53
$160.94
$238.28
$349.90
$385.62
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
Year of Msp Dos
Msp Funnel
70 Addre

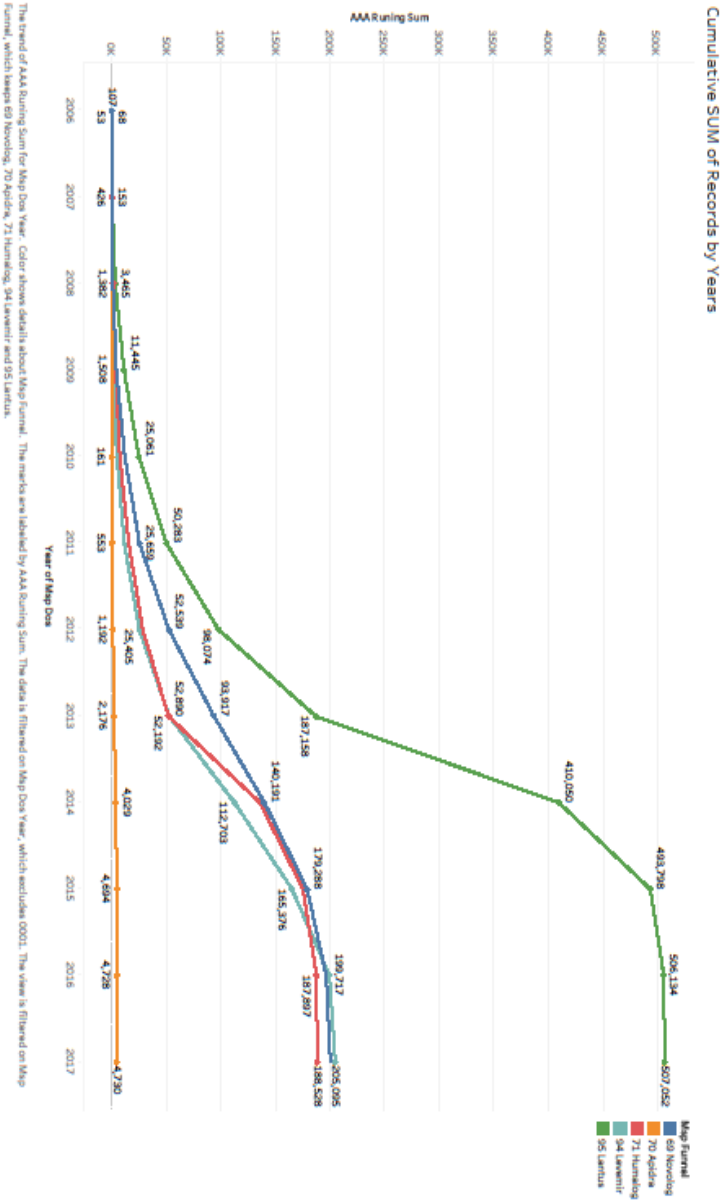
64. As shown by the above graphs, over the past ten years, Plaintiffs has been forced to pay supra-competitive prices for insulin, with prices increasing as much as 788%.

The Insulin Market is Enormous.

65. Millions of consumers of insulin and their medical insurance providers depend on the drug and are captive to the market manipulation and other harmful aspects of Defendants' pricing scheme that has unlawfully hiked the price of this life saving drug.

66. Below is the number of unique instances that Plaintiffs' (assignee's) based on Plaintiffs' own data and statistical compilation and based on Plaintiffs' refined and unique data processing paid for insulin.[62]

[62] The graphs are based on claims data assigned to Plaintiffs.



The trend of AAA Running Sum for Map Dos Year. Color shows details about Map Funnel. The marks are labeled by AAA Running Sum. The data is filtered on Map Dos Year, which excludes 0001. The view is filtered on Map Funnel, which keeps 69 Novolog, 70 Apidra, 71 Humalog, 94 Levemir and 95 Lantus.

67. As the above graph illustrates, Plaintiffs' Assignors have provided over one million prescriptions of insulin in the past ten years.

68. Revenue from the top selling analog insulin manufacturers tops $15.9 billion ($6.98 billion for Sanofi's Lantus and $376 million for its Apidra; $3.03 billion for Novo Nordisk's NovoLog and $2.68 billion for its Levemir; and $2.84 billion for Eli Lilly's Humalog).

Medicare Allegations

69. Plaintiffs is the assignee of Medicare Part C and/or Medicare Part D prescription drug coverage providers on behalf of thousands of individual beneficiaries.

The Social Security Act

70. The Medicare Act is found within the Social Security Act under Title XVIII. The Social Security Act was enacted on August 14, 1935. *See Soc. Sec. Admin., https://www.ssa.gov/history/1930.html (last visited Oct. 27, 2016)*. A few years thereafter, the law added benefits for a retiree's spouse, as well as children and disability benefits. Id. It is "the foundation of economic security for millions of Americans—retirees, disabled persons, and families of retired, disabled or deceased workers. About 163 million Americans pay Social Security taxes and 59 million collect monthly benefits. About one family in four receives income from Social Security." *See* Nat. Academy of Soc. Ins., https://www.nasi.org/learn/socialsecurity/overview (last visited Oct. 27, 2016).

71. The Social Security System uses taxpayer money to pay benefits to retirees, the disabled, survivors of workers who have died, and dependents of beneficiaries. *See Understanding the Benefits, Social Security Administration, 4 (March 2016), https://www.ssa.gov/pubs/EN-05-10024.pdf*. Any unused money goes to the Social Security trust fund. Id. "Nearly 84 percent of all people 65 and older ("Seniors") receive social security." *Nat. Academy of Soc. Ins., 4 (Aug.*

2016), https://www.nasi.org/sites/default/files/research/2016_Social_Security_Primer.pdf (last visited Oct. 27, 2016). In 1965, Congress amended the Social Security Act to create the Medicare Act under Title XVIII.

The Medicare Act

72. The Medicare Act functions as a "federally funded health insurance program for the elderly and the disabled." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1993). The Medicare Act consists of five parts — Part A, B, C, D and E. Part A and Part B "create, describe, and regulate traditional fee-for-service, government-administered Medicare." *In re Avandia Mktg. Sales Practices and Products Liability Litigation*, 685 F.3d 353, 357 (3d Cir. 2012) (citing 42 U.S.C. §§ 1395c to 1395i-5; 1395j to 1395w). Part C outlines the Medicare Advantage program and provides that Medicare beneficiaries may elect for private insurers to deliver their Medicare benefits to them. 42 U.S.C. §§ 1395w-21-29. Further, Part D provides for prescription drug coverage to Medicare beneficiaries, and Part E contains miscellaneous provisions related to 42 U.S.C. §§ 1395x, 1395y.

73. An enrollee's health coverage with an MAO is strictly construed and regulated by CMS. *Id*. So much so that CMS provides detailed templates for MAOs to use when they create documents, including an evidence of coverage that is provided to enrollees. *See* CMS, https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html (last visited October 27, 2016).

74. In essence, **Medicare Part C is the functional equivalent of Original Medicare**. *See* 42 C.F.R. §§ 422.108(f), 422.101; *Honey v. Bayhealth Med. Ctr., Inc.*, 2015 Del. Super. LEXIS

378, at *18 (Del. Super. Ct. July 28, 2015) (holding "an MAO is squarely within the traditional Medicare system").

The Medicare Part C Program

75. Since the 1970s, Medicare beneficiaries have had the option to receive their Medicare benefits through private health plans, mainly Health Maintenance Organizations ("HMOs"), as an alternative to the federally administered traditional Medicare programs. Kaiser Family Foundation, http://kff.org/medicare/fact-sheet/medicare-advantage/ (last visited October 26, 2016). The Balanced Budget Act of 1997 named Medicare's managed care program "Medicare+Choice" and the Medicare Modernization Act (MMA) of 2003 renamed it "Medicare Advantage." *Id., See also Collins v. Wellcare Healthcare Plans, Inc*., 73 F. Supp. 3d 653, 659 (E.D. La. 2014). "The congressional goal in creating the Medicare Part C option was to harness the power of private sector competition to stimulate experimentation and innovation to create a more efficient and less expensive Medicare system." D. Gary Reed, Medicare Advantage Misconceptions Abound, 27 Health Law 1, 3 (2014). Congress sought to achieve this goal by implementing a program wherein the government would pay private health insurers a flat rate per enrollee to administer and provide the same basic benefits received under traditional Medicare. *See Honey v. Bayhealth Med. Ctr., Inc*., 2015 Del. Super. LEXIS 378, at *7-17 (Del. Super. Ct. July 28, 2015). Pursuant to this framework, an MAO pays providers directly for the care received by Part C enrollees. *Id*. at *10. To the extent that this care exceeds the flat rate received from the government, an MAO assumes the risk and cost. *Id*. In the event that care costs less than the flat rate received, an MAO is permitted to keep the difference as a profit. *Id.*

76. To be approved to be an MAO, a private insurer must enter a bidding process, meeting certain threshold requirements. *Id*. MAOs must also be licensed in each State in which

they operate. *Id*. MAOs must offer an "[evidence] of coverage" annually, approved by CMS to enrollees. Id. In providing the basic benefits offered to traditional Medicare enrollees, MAOs must abide by national coverage determinations provided by CMS. *Id*. In addition, all coverage disputes between enrollees, and MAOs must go through the traditional Medicare appeals process. *Id*. at *11. The decisions coming out of the Medicare appeals process are, moreover, binding upon an MAO. *Id*.

77. It is the federal government which sets the fixed rate at which MAOs will be remunerated. *Id*. at *12. Likewise, the federal government establishes the basic services that each Part C private insurer participant must provide. *Id*. These private health insurers are, further, constrained in their ability to deny coverage, limited to the decisions of federally anointed adjudicators. *Id*. The discretion permitted to these private insurers is within this federally created framework – not outside or even alongside it. *Id*. at *12-13. Under Part C, the contract is between the federal government and the insurer. *Id*. at *13.

78. By way of background, Plaintiffs' Assignors entered into a contract with CMS to provide Medicare benefits in accordance with the Medicare Part C program to Medicare-eligible enrollees like E.M. and, in return, received a per capita fee from CMS. *See* Humana *Med. Plan, Inc. v. W. Heritage Ins. Co*., 2016 U.S. App. LEXIS 14509, at *11 (11th Cir. 2016) ("Under the Medicare Advantage program, a private insurance company, operating as an MAO, administers the provision of Medicare benefits pursuant to a contract with CMS. CMS pays the MAO a fixed fee per enrollee, and the MAO provides at least the same benefits as an enrollee would receive under traditional Medicare."); *See also* 42 U.S.C. §§ 1395w-22(a), 1395w-23. Therefore, the defining factor of a truly private insurance plan, one between insured and an insurer, is lacking. *See W. Heritage Ins. Co*., 2016 U.S. App. LEXIS 14509 at *11. *Id*.

79. In sum, MAOs are more akin to traditional Medicare, rather than a private health insurance plan. *Id*. at *16-17 ("There is no such thing as a [M]edicare Advantage insurance policy."). Medicare Advantage is, instead, a federal program. *Id*.

Medicare Part D

80. Medicare Part D coverage is voluntary prescription drug benefits program for Medicare beneficiaries established in 2003. A beneficiary may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B.

81. Unlike Parts A and B, yet similar to Medicare Part C, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans.

82. The Part D plan sponsor must provide qualified prescription drug coverage which includes "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits.

83. A Plan D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month cost estimate for providing Part D benefits to an average Medicare beneficiary in the geographic area.

84. If the Plan D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium. CMS then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor's standardized bid.

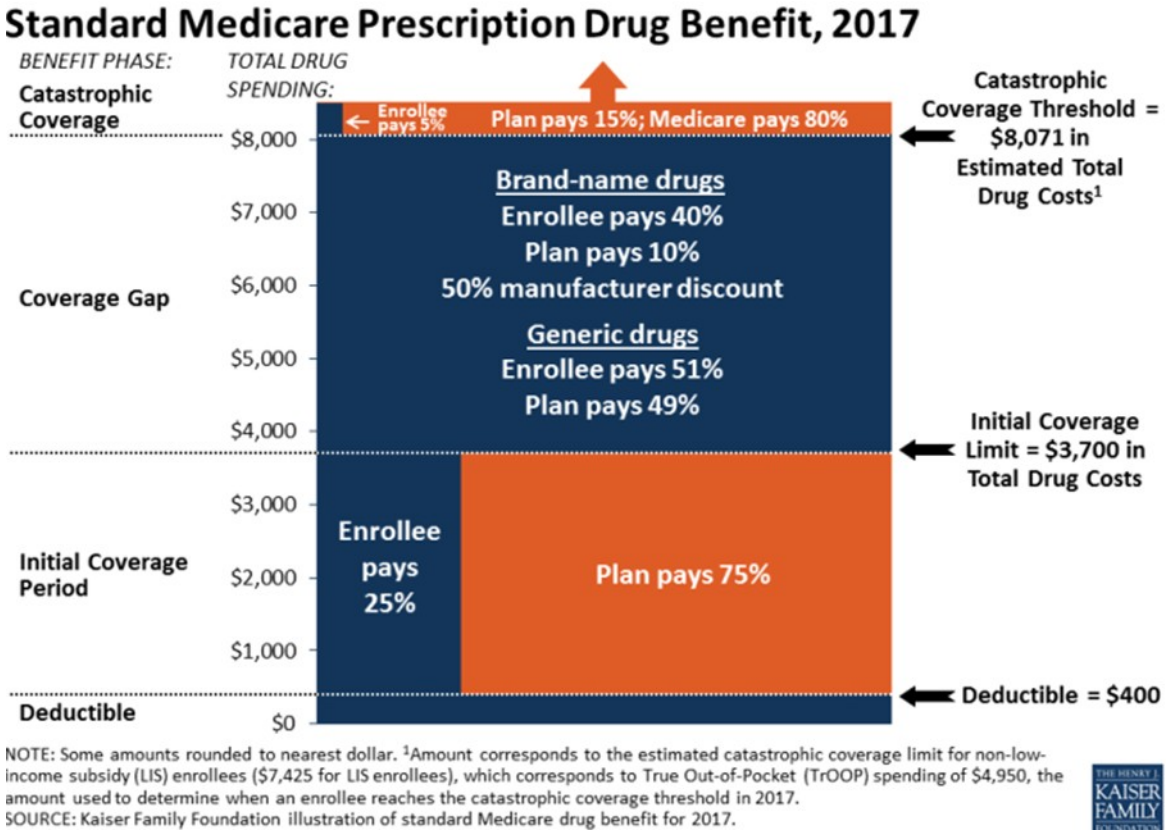
85. As illustrated below, Medicare Part D plan sponsors are also overcharged as a result of the Insulin Pricing Scheme. In 2017, for Medicare Part D beneficiaries, there is an initial $400 deductible phase during which many Medicare Part D plan participants must foot the entire bill

for the inflated cost of insulin.

86. After meeting the $400 deductible, Medicare Part D sponsors are responsible for 75% of all payments in the second phase. Beneficiaries stay in this phase until they and the plan have spent a total of $3,700 on covered drugs. Paying 75% of an inflated price injures these participants.

87. Upon hitting the second coverage breakpoint, the beneficiary is in what is known as the Medicare Part D "Donut Hole," which refers to a coverage gap phase where the beneficiary must pay for branded drugs 40% of the list price, the manufacturer discounts branded drugs by 50%, and the plan pays the remaining 10%. Again, the percentage-of-cost requirement means that inflated insulin prices hurt Part D sponsors in this third coverage phase.

88. A beneficiary leaves the coverage gap and is covered again after spending total $4,950 out-of-pocket—which is also when total drug costs covered by the participant, the plan, and discounts reach $7,425. At which point, the Part D Sponsor pays 15% of the list price, while original Medicare pays 80%.



The False Claims Act

89. The False Claims Act (FCA), 31 U.S.C. §§ 3729 – 3733, was enacted in 1863 by Congress, which, at the time, was concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army. The FCA provided that any person who knowingly submitted false claims to the government was liable for double the government's damages plus a penalty of $2,000 for each false claim.

90. Specifically, liability under the FCA is triggered if any person knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or conspires to commit such action. *See* 31 U.S.C. § 3729(a)(1)(B-C).

91. A person knowing or knowingly committed the violation if they: (i) had actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the

information; or (iii) acts in reckless disregard of the truth or falsity of the information. *See* 31 U.S.C. § 3729(b)(1).

92. A claim made to the government includes any request or demand, whether under a contract or otherwise, for money that is made to a contractor, grantee, or other recipient, if the money is to be spent or used on the Government's behalf, or to advance a Government program, and if the United States Government provides or has provided any portion of the money requested or demanded. *See* 31 U.S.C. § 3729(b)(2).

The Anti-Kickback Statute

93. Soon after the establishment of the Medicare and Medicaid programs unethical provider practices began to develop. Problematic arrangements took various forms, including percentage lease agreements and payment of test interpretation fees to physicians who referred testing without performing the interpretation themselves.

94. To combat these unethical practices, Congress passed the original version of the AKS in 1972. The statute made the receipt of kickbacks, bribes, or rebates in connection items or services covered by the Medicare and Medicaid programs a crime.

95. The AKS makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person to purchase or recommend any goo, service, or item covered under a federal health care program. *See* 42 U.S.C. § 3729(b)(2).

96. Compliance with the AKS is a condition of payment in Federal health care programs. Claims that include items or services resulting from a violation are not payable under Federal health care programs.

97. The foundation of the AKS is based on the realization that kickbacks in health care can lead to overutilization of medical services or products, increased program costs, corruption of

medical decision making, patient steering, and unfair competition.

98. The Affordable Care Act ("ACA") contained provisions that broadened FCA civil liability to include violations of the AKS. *See* 42 U.S.C. § 1320(a)-7b(g).

99. Thus, a violation of the AKS – even if the service or item was medically necessary, provided, and appropriately billed – constitutes a *per se* violation of the FCA.

100. Further, the ACA amended the ACA to provide that "a person need not have actual knowledge … or specific intent to commit a violation." *See* 18 U.S.C. § 1347(b).

101. Essentially, actual knowledge of an AKS violation or the specific intent to commit a violation of the AKS is not necessary.

102. It is enough that a defendant knew, or should have known (a disregard of readily available information in the profession), that the conduct was generally unlawful.

The Insulin Pricing Scheme.

103. Plaintiffs' Medicare plan enrollees are required to pay a "Copay" or "Coinsurance" for prescription drugs, in order to share the cost of prescription drugs. These Medicare enrollees must also must pay deductibles. They participate in percentage-based cost-sharing for insulin purchases in multiple coverage phases.

104. In the case of insulin, the prices that Plaintiffs pays are inflated due to Defendants' Insulin Pricing Scheme, which generates kickbacks to the PBM Defendants and sales for the Drug Manufacturer Defendants.

Defendants' Concealment of the Insulin Pricing Scheme.

105. In their advertising and marketing materials, and in all other extra contractual communications with Plaintiffs, Defendants have not disclosed their Insulin Pricing Scheme.

106. Nor have Defendants disclosed the Insulin Pricing Scheme to Plaintiffs, whether

before or after their enrollment.

107. Defendants keep secret the number of rebates that the Drug Manufacturer Defendants pay for placement on the PBM Defendants' formularies. Likewise, the PBM Defendants keep secret the portion of the rebates and other payments form the Drug Manufacturer Defendants that they pocket. Defendants conceal that the purpose and effect on the Insulin Pricing Scheme is to drive up the list price of insulin while maintaining the net prices paid by the PBM Defendants so that ever larger rebates can be paid without affecting the Drug Manufacturer Defendants' profits.

The Pharmaceutical Supply Chain.

108. The pharmaceutical supply chain in the United States consists of four major actors: Drug Manufacturers, Wholesale Distributors, Pharmacies, and PBMs.

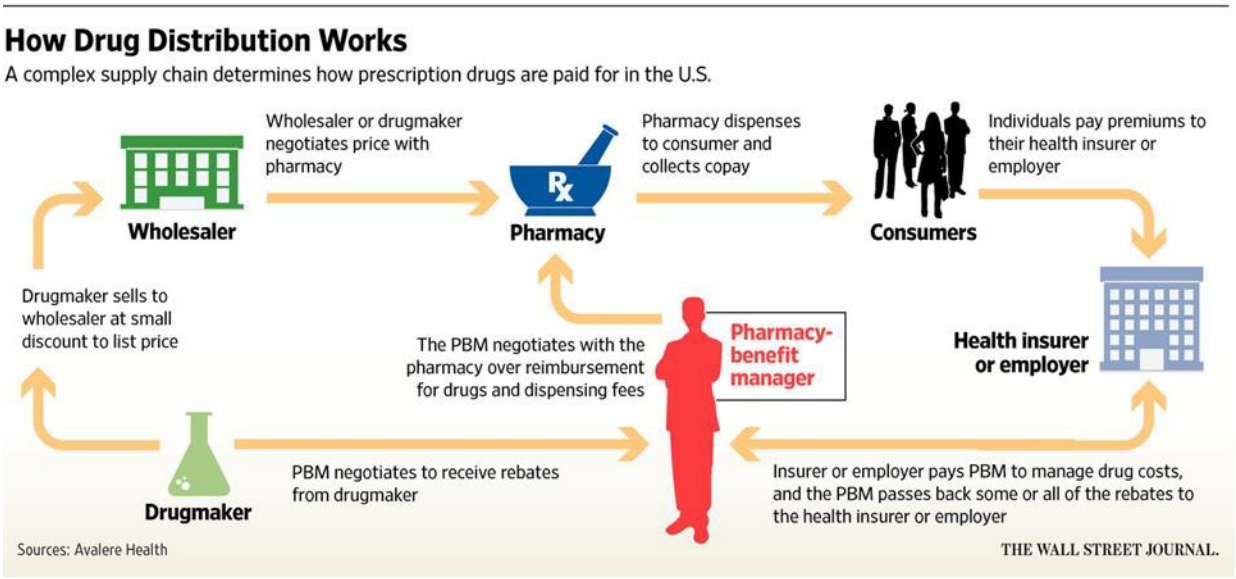
109. Pharmaceutical products: originate in manufacturing sites; then are transferred to wholesale distributors (in the case of insulin); are stocked at retail, mail-order, and other types of pharmacies; are subject to price negotiations and processed through quality and utilization management screens by PBMs; are dispensed by pharmacies; and ultimately are delivered to and taken by patients.

110. The technical function of a PBM is to administer a health coverage provider's prescription drug program. A PBM develops the coverage provider's drug formulary (the list of drugs included in coverage at various pricing "tiers"), processes claims, creates a network of retail pharmacies that provide discounts in exchange for access to a provider's plan participants, and negotiates with pharmaceutical manufacturers. PBMs also contract with a network of retail and community pharmacies.

111. In addition, and of significance here, PBMs have contractual relationships with

pharmaceutical manufacturers and pharmaceutical wholesalers. PBMs negotiate rebates, fees, and other concessions with the manufacturers. These relationships allow PBMs to exert tremendous influence and control over what drugs are made available to health plans and insureds.

112. The following chart illustrates the pharmaceutical supply chain, and the PBMs' central role in it:



The Rise of the PBMs in the Pharmaceutical Supply Chain.

113. In the 1990s, drug manufacturers began acquiring PBMs, which caused an egregious conflict of interest, prompting the Federal Trade Commission to undo those deals. The deals allowed drug manufacturers to coordinate pricing policies, see their competitors' sensitive pricing information, and favor their own drugs over those of their competitors.

114. In the early and late 2000s, PBMs started buying pharmacies, which has caused a similar conflict of interest as resulted from the merger of drug manufacturers and PBMs in the 1990s. When a PBM combines with a pharmacy, they lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may

collude in them. The power of the largest PBMs has continued to grow, and has allowed them to distort the pharmaceutical supply chain to their own financial advantage.

115. Drug manufacturers understand the power of PBMs. Because of their size, and the many thousands of health plan clients they represent, PBMs can steer business from one drug manufacturer to another based on which one pays the larger PBM kickback.

116. PBMs maximize profits by exploiting the United States' complex pharmaceutical distribution system. While the role of PBMs in the supply chain is well known, the size of the rebates and other fees they extract from drug companies for formulary placement, and the portion of these payments they pocket (the "PBM kickbacks") is a carefully guarded secret.

117. PBMs depend on the lack of transparency to conduct their business and have vigorously resisted any requirement that they disclose the details of their agreements with drug manufacturers, and the kickbacks they receive from them..

118. PBMs manage pharmacy benefits for over 266 million Americans. Two large companies dominate the PBM market: Express Scripts, and CVS Health. Together, these companies cover over 50% of insured Americans.

119. Business for the PBM Defendants is booming. For example, from 2014 to 2015, Express Scripts' net income increased by $468.8 million, or 23.4 percent. During the same time, gross profit for CVS Health's pharmacy services segment, which includes the PBM CVS Caremark, increased 9.6 percent.

120. The PBM Defendants' earnings increased further in 2016. Express Scripts' net income increased 37.5 percent from 2015 to 2016. CVS Health's gross profits from its pharmacy services segment increased by an additional 9.6 percent.

The Insulin Pricing Scheme: Rebates Gone Awry.

121. PBMs turn a profit in three primary ways: first, their health insurer clients pay them service fees for processing prescriptions and operating mail-order pharmacies; second, insurers pay transaction fees on the different operations required to manage the complex cash flows between insurers, pharmacists and manufacturers; and third, PBMs take a cut of the drug "rebates" and other fees they negotiate with drug companies.

122. This rebate arrangement, if operated ethically and honestly, would create an incentive for PBMs to negotiate *lower* net drug prices: if PBMs could purchase drugs more cheaply from the drug companies, they could increase their margins when they sell the drugs to their clients. Indeed, PBMs have the greatest leverage to negotiate lower prices when two or more drug companies make ostensibly interchangeable products—*i.e.*, drugs within the same therapeutic class. In such a scenario, the drug companies should compete on price, as in normal competitive markets, for the PBMs' business.

123. However, the arrangement is not operated ethically and honestly. The Drug Manufacturer Defendants and PBMs are gaming the system. They have realized that they both benefit if, instead of forcing the Drug Manufacturer Defendants to sell their drugs to the PBMs for cheaper, they induce the Drug Manufacturers to raise their publicly reported list price, but largely maintain the net prices. This creates what is, in effect, a massive slush fund derived from the difference between the net and list prices that can be used by the Drug Manufacturer Defendants to pay the larger and larger rebates demanded by the PBM Defendants for formulary placement.

124. The scheme allows the Drug Manufacturer Defendants to maintain their profit margins on drugs sold in the United States and ensure their access to the millions of Americans whose drugs are made available via the PBM formularies. And, the scheme allows the PBM Defendants to leverage their control over formularies to obtain PBM kickbacks. With net prices

staying the same, and list prices going up, the rebates get bigger, and so does the PBM Defendants' cut. The scheme artificially drives up list prices specifically so the PBM Defendants can earn more profit from the rebates they pay to the PBM Defendants behind the scene. And the Drug Manufacturers can pay the PBM Defendants what they demand without significantly impacting the Drug Manufacturers profits.

125. Thus, far from using their prodigious bargaining power to lower drug prices, the PBM Defendants abuse their position to benefit both themselves and the Drug Manufacturer Defendants. It is a profitable enterprise, though deeply unethical and damaging to those who shoulder the burden of the higher list prices. This dynamic lies at the heart of the surging cost of insulin, and the resulting public health disaster.

The List/Net Price Divergence.

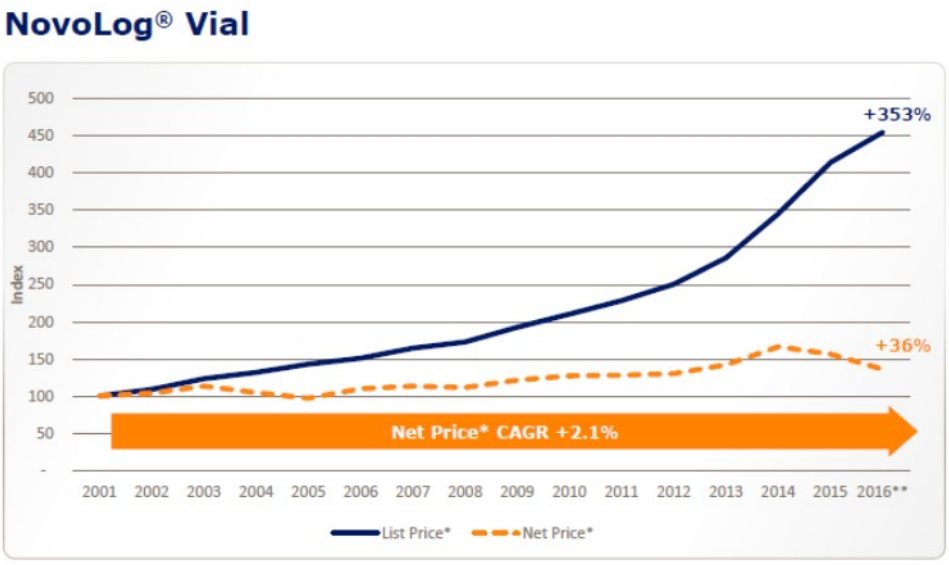
126. While the Defendants often obscure the true net realized prices for insulin and other drugs, the escalating list price is a matter of public record. As noted above, the list prices for the analog insulins have skyrocketed largely in lock-step. Indeed, in 13 instances since 2009, Sanofi and Novo Nordisk raised the list prices of their long-acting analog insulins, Lantus and Levemir, in tandem. Eli Lilly and Novo Nordisk have engaged in the same lock-step behavior with respect to their rapid-acting analog insulins, Humalog and Novolog.

127. The question, then, is why aren't the Drug Manufacturer Defendants competing on price? They sell similar, and in many ways interchangeable drugs, and have been for years. Indeed, the drugs are the same as they were ten years ago, and the clinical benefit of the drugs is unchanged. Yet, the list price keeps going up. The answer is the Insulin Pricing Scheme. The Drug Manufacturer Defendants are not competing on price because instead they are competing on rebates and other fees paid to the PBM Defendants, and the profits the PBMs make on these fees.

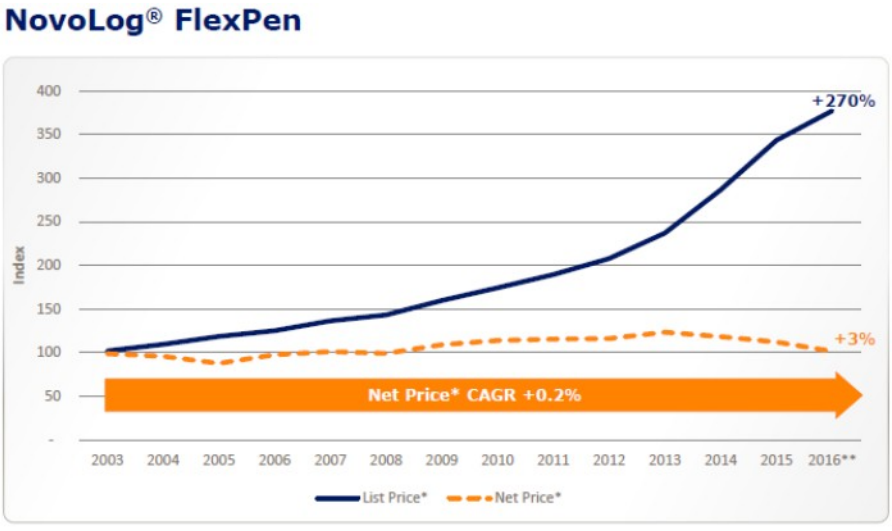
This anti-competitive, market-distorting conspiracy explains the spectacular rise in insulin list prices, while the real prices that the PBM Defendants pay for insulin, and hence the net prices realized by Manufacturers remain relatively constant.

128. The figures below—included in a press release by Novo Nordisk—illustrate this phenomenon. Note that the figures below show percentage price changes, not dollar amounts.

NovoLog Vial Net Versus List Price Increases:



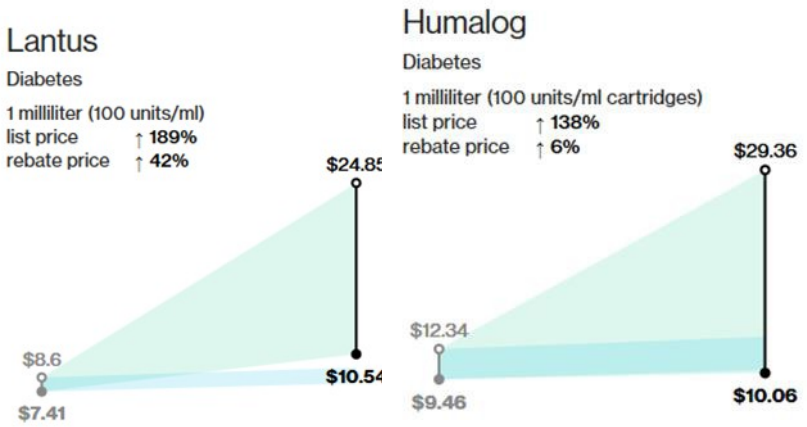
NovoLog FlexPen Net Versus List price increases:



129. As indicated in the below diagrams prepared by SSER Health, a health- industry

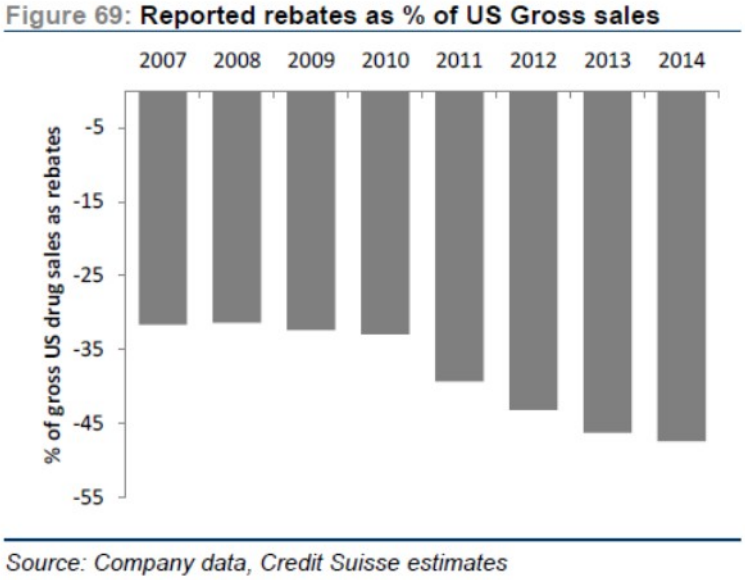
research firm, the same widening spread has occurred for the other major analog insulins:

SSER Health Diagrams:



130. Sanofi, Novo Nordisk, and Eli Lilly's spread-increasing behavior is also visible from data on these companies' aggregate rebates to PBMs and insurers. The two figures below illustrate Novo Nordisk's aggregate rebates from 2007 to 2014.

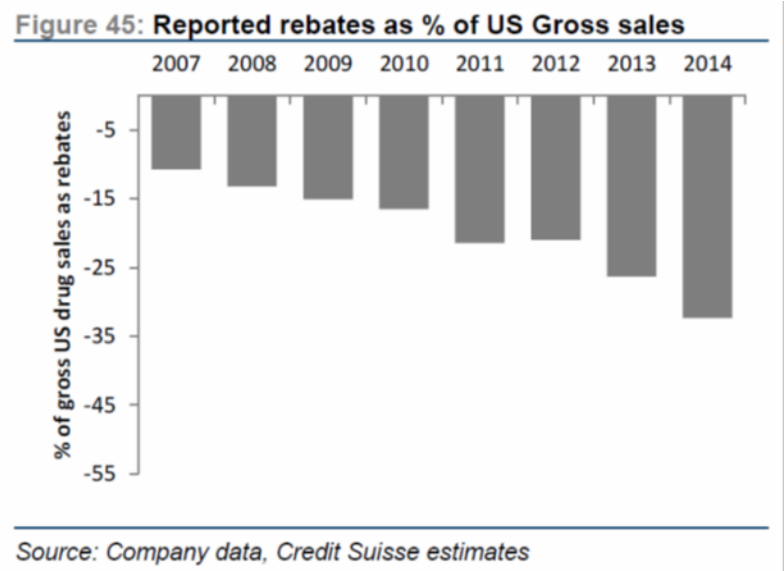
Novo Nordisk's Reported Rebates as a Percentage of U.S. Gross Sales from 2007-2014:



131. Finally, Eli Lilly has greatly increased its rebates off the inflated list prices. Figures

19 and 22 show the amount Eli Lilly has increased its rebates (spreads) from 2007 to 2014. Contrary to Novo Nordisk, for which insulin represents a substantial amount of gross revenues, Eli Lilly is an extremely diversified manufacturer. As a result, the impact of the very steep insulin rebating that has gained Lilly the lion's share of the U.S. insulin market in recent years is attenuated in the graph below by less aggressive rebating on other drug classes.

Eli Lilly's Reported Rebates as a Percentage of U.S. Gross Sales from 2007-2014:



The Drug Manufacturer Defendants Admit the Insulin Pricing Scheme and its Impact on Patients.

132. The Drug Manufacturer Defendants have come up with a variety of excuses for the escalating insulin list prices. For example, Novo Nordisk offered as one justification the "clinical benefit" of their drugs—a nonsensical explanation given that both the drugs and the benefits have been the same for years. Yet, in the face of widespread criticism of insulin prices spinning out of control—the Drug Manufacturer Defendants have admitted the true reasons for the price escalation.

133. On November 30, 2016, Novo Nordisk issued a press release stating:

> We hear from more and more people living with diabetes about the challenges they face affording healthcare, including the medicines we make. . . News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the "list price" increases we've made over the last decade. In other words, a list price increase by **XX percent leads to an automatic XX percent profit** for the drug maker. We believe that is misleading and here's why: As the manufacturer, we do set the "list price" and have full accountability for those increases. However, after we set the list price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the "net price." The net price more closely reflects our actual profits.

134. In its 2016 annual report, Novo Nordisk admitted to the practice of exchanging rebates for preferential formulary placement noting that: "Increasingly, PBMs and health plans play a key role in negotiating price concessions with drug manufacturers on behalf of private payers for both the commercial and government channels, and determining the list of drugs covered in the health plan's formulary. Specifically, . . . Payer pressure to reduce the overall drug costs has resulted in greater focus on negotiating higher rebates from drug manufacturers. Private payers are increasingly keen to adopt narrow formularies that exclude certain drugs, while securing increased rebates from the preferred brand." As a consequence, the report stated, Novo Nordisk has announced contract negotiations for 2017 with higher-than-anticipated rebates to obtain broader coverage for its products.[78]

135. Eli Lilly, too, has admitted that it raises list prices as a *quid pro quo* for formulary positions: "[t]he reason drug makers sharply raise benchmark prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists."

[78] Novo Nordisk Inc., Annual Report, Letter from the Chairman (February 1, 2017). *See also* Novo Nordisk Inc., Annual Report, Letter from Lars Rebien Sørensen, (February 1, 2017) (stating "[i]n 2017, we will see lower net prices in the U.S. as we had to increase the rebates we offer the pharmaceutical benefit managers (PBMs) in order to ensure broad market access for our products).

136. In June 2016, CEO of Eli Lilly, John C. Lechleiter, further explained that those "higher rebates can be an incentive for a payer to stick with—with essentially a higher-priced product."

137. Sanofi has admitted to the same practices. In February 2015, Peter Guenter, Sanofi's Executive Vice President, explained that: "As expected, increased rebates in the U.S. to secure favorable formula repositions for Lantus with key payers have kicked in since January 1, 2015."

138. The Drug Manufacturer Defendants, thus, acknowledge that the Insulin Pricing Scheme drives up list prices. While the message they appear to be trying to send is that the "PBMs made them do it," the fact of the matter is they could compete for access to formularies by lowering the list prices for their insulin products and refusing to rebate. This, however, would cut into their bottom line. as it would involve the Manufacturers in direct competition on price.

139. While not "real" for the PBM Defendants, the list price is real for MAOs. Even with price negotiation, an artificially high "base price" is still harmful and unlawful. Thus, the Insulin Pricing Scheme benefits the Drug Manufacturer Defendants and PBM Defendants at the expense of almost all prescription insulin consumers and third-party payers. Furthermore, Medicare Part D beneficiaries are also left paying inflated amounts in all phases as soaring prices cause them to speed toward the Donut Hole.

140. The result of Defendants' scheme is that MAOs are saddled with costs based on inflated prices and Part D sponsors are powerless in maximizing benefits prior to their beneficiaries being in the "donut hole" and the subsequent catastrophe level of Part D benefits.

High List Prices Directly Impact Plaintiffs' Ability to Provide Benefits.

141. A drug that used to cost seven cents a week in 1924, today now costs hundreds of

dollars a month. Plan D beneficiaries they are generally on a fixed income, some beneficiaries may not be able to afford the "donut hole" price of insulin, these beneficiaries are forced to sacrifice their health and compromise their treatment regimen thus placing them in a higher likelihood of hospitalization for which Medicare would be responsible for.

142. Doctors are speaking up about the number of diabetes patients coming in with poorly controlled blood sugar who explain that they were not taking their insulin because of its expense. Patients who are worried about the cost of insulin may ration their insulin, frequently not taking it when they need to, cutting their doses in half, or refilling their pump hours after the insulin runs out, even though it means their blood sugar will go up. Patients may also deprive themselves of food to keep their blood sugar low and avoid the need for insulin.

143. The less controlled an individual's blood sugar is, the higher their risk for diabetes-related complications. As noted above, these complications include cardiovascular disease, nerve damage that can lead to amputation of limbs, kidney disease and failure, eye damage such as blindness or glaucoma, skin conditions, hearing impairment, and Alzheimer's disease.

144. The American Diabetes Association estimates that the average person diagnosed with diabetes has about $13,700 in medical expenditures each year, of which about $7,900 is attributable to diabetes. Costs for people with type 1 diabetes are typically much higher, as the ADA averages include many type 2 patients who are able to manage on low-cost oral medications alone.

145. The financial burden of diabetes means that many beneficiaries, in the "donut hole", do not receive the care they need for a disease that has been treatable for almost a century. In addition, the uncertainty of being able to pay for the insulin that is necessary for their survival leaves many individuals in a constant state of stress and anxiety. Insulin rationing is common, as

is patients allowing themselves to go into DKA to get insulin in emergency rooms.

146. While the PBM Defendants continue to conceal the amount, they make on kickbacks, the Drug Manufacturer Defendants have attempted to blunt criticism through various actions. For example, in its November 30, 2016 press release, Novo Nordisk made a modest commitment to limit any potential future list price increases for medicines to no more than single-digit percentages annually. Similar statements made on behalf of other manufacturers have occurred as well.

147. The measures do not end or even address the insidious practice of competing for the PBM Defendants' business based on the rebate provided to the PBMs, and the kickbacks derived from the rebate. The structural problems that have caused the escalation of the list price for insulin remain, and Insulin Rebate Scheme continues. The Defendants continue to game the system, and third-party payers covering beneficiaries with diabetes continue to pay the price.

148. The fact remains that the insulin market in the United States is an ideal source of profit for unethical middlemen and drug manufacturers like the Defendants. About six million Americans use insulin. Although it has been commercially produced for almost a hundred years, in the United States only three major pharmaceutical companies hold patents that allow them to manufacture the drug. These three manufacturers "compete" with each other not on price, but by offering ever-steeper discounts for insulin to another select group—a handful of PBMs who profit from every list price increase through the kickbacks they receive. The result is a staggering abuse of power and trust. The Defendants are gaming the system, and people with diabetes are paying the price.

CLASS ALLEGATIONS

149. Plaintiffs brings this action on behalf of itself and the following classes:

Class 1: Entities that contracted directly with the Centers for Medicare and

Medicaid Services ("CMS") or their assignees pursuant to Medicare Part C, who purchased, paid, provided reimbursement, and/or possess the recovery rights to reimbursement, for some or all of the purchase price of Defendants' insulin pursuant to Medicare Part C contracts offering Medicare Parts A and Part B services from January 1, 2011, to present. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; and (c) any judges or justices involved in this action and any members of their immediate families.

Class 2: Entities that contracted directly with the Centers for Medicare and Medicaid Services ("CMS") or their assignees pursuant to Medicare Part D, who purchased, paid, provided reimbursement, and/or possess the recovery rights to reimbursement, for some or all of the purchase price of Defendants' insulin pursuant to Medicare Part D contracts providing services from January 1, 2011, to present. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; and (c) any judges or justices involved in this action and any members of their immediate families.

150. Plaintiffs brings this action pursuant to Federal Rule of Civil Procedure 23 both individually and on behalf of all MAOs who have contracted with CMS to provide coverage for thousands of beneficiaries and individuals such as S.E. and all other individuals similarly situated which claims have been assigned to Plaintiffs that comprise (a) national injunctive class and/or (b) national damage classes and/or (c) various state-wide damage sub-classes, during the period from January 1, 2011, to the present.

151. As discussed in this Class Action Complaint, Defendants have enjoyed ill-gotten gains from the sales of insulin at the expense of individual beneficiaries and Class Members suffering damages to their property and business. Such damages apply to all individual Class Members (and Plaintiffs as the rightful assignee of those organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, when a company engages in conduct that has uniformly harmed a large number of claimants such as Plaintiffs, other third-party payers, and consumers, class resolution is an effective tool to redress the harm.

152. Here, the Class Members have been deprived of property and money by being

caused to purchase prescriptions of insulin at unlawfully high prices and volumes as a direct result of Defendants engaging in racketeering activity and anti-competitive conduct, as alleged throughout this Complaint.

153. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy:

a. Numerosity: Numerous MAOs assigned their rights to Plaintiffs, individual MAOs represent thousands of beneficiaries, like S.E., that purchased insulin throughout the United States, including, like S.E., Converse, Texas. The MAOs were forced to pay artificially inflated, supra-competitive prices for insulin. Thus, the numerosity element for class certification is met.

b. Commonality: Questions of law or fact are common to all members of the Class. Defendants' illegal pattern of racketeering activity and unlawful conduct having a common, adverse effect on all purchasers of insulin, specifically, MAOs, who are left without an option but to pay Defendants' illegally obtained prices for beneficiaries like S.E. Therefore, common questions of law or fact are prevalent throughout the class, i.e., whether Defendants engaged in a pattern of racketeering activity and conspired to substantially increase prices of insulin. Each Class Member shares the same needed remedy, i.e., reimbursement for the inflated prices and lost money due to the Defendants' racketeering activity, disgorgement of the Defendants' profits from the illegal venture, and imposition of injunctive and equitable relief to stop Defendants from continuing in their activities.

c. Typicality: Plaintiffs' claims are typical of the claims of the Class because their claims, such as those claims paid on behalf of S.E., who purchased insulin at the Wal-Mart in Converse, Texas arise from the same course of conduct by Defendants, i.e., racketeering activity and artificially inflating prices. Plaintiffs' Assignors paid

or reimbursed for prescriptions of insulin at supra-competitive prices and as a consequence of Defendants' pattern of racketeering activity. Plaintiffs' claims are, therefore, typical of the Class.

d. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the Class. Its interests in vindicating these claims are shared with all members of the Class. In addition, Plaintiffs is represented by competent and experienced counsel in class action litigation.

154. The Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Class. Defendants deliberately conspired to drive up prices of insulin by engaging in a pattern of racketeering activity, thus depriving both Plaintiffs as assignee of the right to recovery of thousands of individual Class Members of their right to pay prices that have been set by the dynamics of a competitive market.

155. The Class is also properly brought and should be maintained as a class action under Rule 23(b)(2) and (b)(3). Defendants have acted or refused to act on grounds that apply generally to the Class, such that final injunctive relief or corresponding declaratory relief is appropriate with respect to the class. Additionally, Defendant's acted in such a way that questions of law or fact predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

156. Plaintiffs alleges that it would have paid significantly less for insulin if Defendants had not engaged in racketeering conduct.

CLAIMS FOR RELIEF

COUNT I

VIOLATIONS OF 18 U.S.C. §1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961, *ET SEQ.*
(Against Defendants CVS Health, Sanofi, Novo Nordisk, and Eli Lilly)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

157. Plaintiffs bring this Count against Defendants CVS Health, Sanofi, Novo Nordisk, and Eli Lilly (collectively, for purposes of Count I, the "CVS Health RICO Defendants").

158. At all relevant times, the CVS Health RICO Defendants have been "persons" under 18 U.S.C. § 1961(3) because they can hold, and do hold, "a legal or beneficial interest in property."

159. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

160. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

161. As explained in detail below, Defendant CVS Health sought to infiltrate the business arrangement established between three insulin drug manufacturers–Sanofi, Novo Nordisk., and Eli Lilly–health plans and prescription drug insurance companies across the country through a fraudulent scheme designed to secure greater profits and market share, increase the cost of insulin medication, secure a favorable formulary position for Sanofi's, Novo Nordisk's, and Eli Lilly's insulin products, and extract hundreds of millions of dollars of revenue from Plaintiffs' Assignors. As explained in detail below, the CVS Health RICO Defendants' misconduct violated sections 1962(c) and (d).

162. As evidenced by Defendant CVS Health's formulary placements and exclusions

throughout the class period[79] coupled with statements from Manufacturer Defendants stating that PBMs have forced higher rebates to allow Manufacturer Defendants to be placed on CVS Health's formularies.[80]

A. Description of the CVS Health RICO Enterprise.

163. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). An association-in-fact enterprise requires three structural features: (1) a purpose; (2) relationships among those associated with the enterprise; and (3) longevity sufficient to permit those associates to pursue the enterprise's purpose.

164. For years, CVS Health and other pharmacy benefits managers played a small but meaningful role in the prescription drug business: providing administrative services on behalf of health plans that offer prescription drug benefits and negotiating with drug manufacturers on their behalf.

165. In the past decade, however, CVS Health and other PBMs began to exert influence in their role as insurance-industry middle-men to dictate the success or failure of certain drugs in the marketplace by offering to include or threatening to exclude certain medications from some or all of their formularies and, in the process, extracting hundreds of millions of dollars in the form of 'rebate' payments, or kickbacks, from drug manufacturers in exchange for formulary placement.

166. Negotiations between PBMs and drug manufacturers regarding those discounts, however, take place in complex, closed-door meetings, during which PBMs sell access to their formularies in exchange for larger kickbacks, a substantial portion of which they pocket as pure profit.

[79] *See* Composite Exhibit A.
[80] *See* Exhibit B.

167. To facilitate the payment of 'rebates' to PBMs, and ensure their position on certain formularies without impacting their bottom line, the Drug Manufacturers Defendants participate in a scheme with CVS Health to increase the list price of their drugs instead of competing on actual price with other insulin manufacturers.

168. This scheme to increase the profits of PBMs through artificially increasing the list price of medications benefits everyone in the prescription drug industry supply chain except Plaintiffs' assigned individual claimants, who are left paying fraudulently obtained, exorbitant, and ever- increasing prices for its beneficiaries' medications. The practice is particularly pernicious in the case of medications such as insulin, because it decreases access to life-saving drugs. Nevertheless, insulin has become a common target of PBMs, specifically CVS Health.

169. At all relevant times, the CVS Health RICO Defendants, along with pharmacies, wholesalers, and other individuals and entities, including unknown third parties, operated an ongoing association-in-fact enterprise. The sole purpose of this association-in-fact was ensuring that one or more of Drug Manufacturers Defendants products were included on CVS Health's formularies and increasing CVS Health's profits by fraudulently and artificially increasing the list price of those insulin products, thereby giving CVS Health a kickback, at the expense of Plaintiffs and through which the CVS Caremark RICO Defendants conducted a pattern of racketeering activity under 18 U.S.C. § 1961(4).

170. Alternatively, each of the CVS Health RICO Defendants constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the CVS Caremark RICO Defendants conducted their pattern of racketeering activity. The CVS Health RICO Defendants' separate legal statuses facilitated the fraudulent scheme and provided a hoped-for shield from liability for the CVS Health RICO Defendants and their co-conspirators.

171. At all relevant times, the CVS Health RICO Enterprise constituted a single "enterprise" or multiple enterprises within the meaning of 18 U.S.C. § 1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in the CVS Health RICO Defendants' profit-making scheme.

172. The association-in-fact CVS Health RICO Enterprise consisted of the following entities and individuals: (a) CVS Health, its subsidiaries, executives, employees, and agents; (b) Sanofi, its subsidiaries, executives, employees, and agents; (c) Eli Lilly, its subsidiaries, executives, employees, and agents; and (d) Novo Nordisk, its subsidiaries, executives, employees, and agents.

173. While each of the CVS Health RICO Defendants acquired, maintained control of, were associated with, and conducted or participated in the conduct of the CVS Health RICO Enterprise's affairs, at all relevant times, the CVS Health RICO Enterprise: (a) had an existence separate and distinct from each CVS Health RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the CVS Health RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the CVS Health RICO Defendants, along with other individuals and entities, including unknown third parties.

174. The CVS Health RICO Defendants and their co-conspirators, through their illegal CVS Health RICO Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the CVS Health RICO Defendants and the other entities and individuals associated-in-fact with the CVS Health RICO Enterprise's activities by selling insulin products at an inflated and artificial price ("the CVS Health RICO Scheme").

175. CVS Health orchestrated the CVS Health RICO Scheme, whereby CVS Health, as a PBM, leveraged its dominate position in the prescription drug insurance market to demand that

insulin drug manufacturers, like Sanofi, Novo Nordisk, and Eli Lilly, pay substantial kickbacks in order to have their products included or be given priority on CVS Health's formularies.

176. Insulin manufacturers Sanofi, Novo Nordisk, and Eli Lilly facilitated the CVS Health RICO Scheme by agreeing to provide ever-larger 'rebates', or kickbacks, to CVS Health in order to gain or maintain access to its formularies and funding those discounts by artificially increasing the list price of their insulin products.

177. In furtherance of the scheme, the CVS Health RICO Defendants each affirmatively misrepresented or concealed the existence of the inflated and fraudulent nature of these list price increases as well as the existence, amount, and purpose of the kickbacks given to CVS Health to Plaintiffs, consumers, health care payers, and the general public. Specifically, the CVS Health RICO Defendants claimed that the kickbacks paid to CVS Health were for the purpose of lowering drug costs when, in fact, they were *quid pro quo* payments for formulary access that had the opposite effect for Plaintiffs.

B. The CVS Health RICO Enterprise Sought to Fraudulently Increase Defendants' Profits and Revenues.

178. Each CVS Health RICO Defendant benefited financially from the CVS Health RICO Enterprise. CVS Health received direct rebate payments from Sanofi, Novo Nordisk, and Eli Lilly, a large portion of which they pocketed as pure profit, as well as other fees.

179. In exchange, one or more of Sanofi's, Novo Nordisk's, and Eli Lilly's products received a favorable position on one, or several CVS Health's formularies, translating into higher sales and profits for each of these manufacturers. And because the Drug Manufacturer Defendants financed the payment of kickbacks by inflating the list prices for those drugs, they maintained and, in some cases, increased their profit margins.

180. At all relevant times, the CVS Health RICO Enterprise: (a) had an existence

separate and distinct from each CVS Health RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the CVS Health RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the CVS Health RICO Defendants, along with other individuals and entities, including unknown third parties that operated an association-in-fact enterprise, which was formed for the purpose of ensuring that one or more of Sanofi's, Novo Nordisk's, and Eli Lilly's insulin products were included on CVS Health's formularies and increasing CVS Health's profits by fraudulently and artificially increasing the list price of those insulin products at the expense of Plaintiffs, and paying kickbacks from the inflated list price.

181. The CVS Health RICO Defendants and their co-conspirators, through their illegal Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the CVS Health RICO Defendants and the other entities and individuals associated-in-fact with the Enterprise's activities through the illegal scheme to sell insulin products at an inflated and artificial price. Further, CVS Health RICO Defendants committed wire fraud by submitting bills, using interstate wires, for payment that were not in compliance with the AKS and therefore amounted to FCA violations or Medicare fraud.

182. The CVS Health RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement, distribution, and sale of insulin products throughout the country, and the receipt of monies from the sale of the same.

183. Within the CVS Health RICO Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis. The CVS Health RICO Enterprise used this common communication network for purposes of marketing, pricing, and

engaging in negotiations regarding insulin products, their pricing, and placement or position on CVS Health's formularies and for furthering the CVS Health RICO Scheme.

184. Each participant in the CVS Health RICO Enterprise had systematic linkages to each other through corporate ties, contractual relationships, financial ties, and a continuing coordination of activities. Through the CVS Health RICO Enterprise, the CVS Health RICO Defendants functioned as a continuing unit with the purpose of furthering the CVS Health RICO Scheme.

185. The CVS Health RICO Defendants participated in the operation and management of the CVS Health RICO Enterprise by directing its affairs, as described herein. While the CVS Health RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

186. The CVS Health RICO Defendants exerted substantial control over the CVS Health RICO Enterprise, and participated in the affairs of the enterprise by: (a) negotiating and/or offering kickbacks for the insulin products described herein; (b) misrepresenting and/or concealing the existence, amount, or purpose of the kickbacks negotiated for the insulin products described herein; (c) misrepresenting and/or concealing the effect that the negotiated prices had on the price of the insulin products for the third-party payer; (d) negotiating and/or setting the list price for the insulin products described herein; (e) misrepresenting and/or concealing the true cost of the insulin products described herein; (f) publishing, reproducing, and/or distributing documents containing the list price for the insulin products described herein; (g) negotiating and/or offering preferred formulary placement for the insulin product described herein; (h) misrepresenting and/or

concealing the true nature of the relationship and agreements between the members of the enterprise and its effect on the pricing of insulin products; (i) otherwise misrepresenting and/or concealing the inflated and fraudulent nature of the pricing of the insulin products described herein; (j) collecting kickbacks, revenues, and/or profits from the sale of the insulin products described herein; and (k) ensuring that the other CVS Health RICO Defendants and unnamed co-conspirators complied with and concealed the fraudulent scheme.

187. Without each CVS Health RICO Defendant's willing participation, the CVS Health RICO Scheme and common course of conduct would not have been successful.

188. The CVS Health RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in the Defendants' and others' hands.

C. Predicate Acts: Mail and Wire Fraud.

189. To carry out, or attempt to carry out, the scheme to defraud, the CVS Health RICO Defendants, each of whom is a person associated-in-fact with the CVS Health RICO Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the CVS Health RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

190. Specifically, the CVS Health RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

191. The multiple acts of racketeering activity which the CVS Health RICO Defendants

committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the CVS Health RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the CVS Health RICO Enterprise. The CVS Health RICO Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

192. The CVS Health RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions.

193. In devising and executing the illegal scheme, the CVS Health RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs or to obtain money from Plaintiffs by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. To execute the illegal scheme, the CVS Health RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

194. The CVS Health RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

(a) Mail Fraud: The CVS Health RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, price, and/or sell the insulin products described herein by means of false pretenses, misrepresentations, promises, and omissions.

(b) Wire Fraud: The CVS Health RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

195. The CVS Health RICO Defendants' use of the mails and wires include, but are not limited to: (a) the transmission of marketing or other materials indicating, setting, or negotiating the price of the insulin products described herein; (b) the transmission of marketing or other materials indicating or advertising that any of the CVS Health RICO Defendants reduce the price of the insulin products described herein; (c) written, telephone, or electronic communications regarding and/or negotiating the kickback amount of the insulin products described herein;

(d) written, telephone, or electronic communications regarding and/or negotiating kickbacks associated for the insulin products described herein; (e) written, telephone, or electronic communications regarding the existence, amount, or purpose of discounts and/or rebates ("kickbacks") for the insulin products described herein; (f) the transmission and/or distribution of the insulin products described herein through the mails; and (g) the use of the mails or wires to bill for or collect discounts, revenues, and/or profits from the sale of such insulin products described herein.

196. Throughout the class period CVS Health RICO Defendants submitted numerous bills for insulin in violation of the AKS, thus, constituting violations of the FCA.[81]

197. The CVS Health RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships, and other third-party entities in furtherance of the scheme.

198. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct designed to increase the cost of insulin medication and fraudulently extract hundreds of millions of dollars of revenue from Plaintiffs.

199. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire

[81] Plaintiff has been assigned over $250 Million in insulin related claims paid amongst all Defendants.

facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiffs has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described above.

200. The CVS Health RICO Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the CVS Health RICO Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with the CVS Health RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

201. The CVS Health RICO Defendants aided and abetted others in the violations of the above laws.

202. To achieve their common goals, the CVS Health RICO Defendants hid from Plaintiffs, insurers, health plans, and the general public the true net price of the insulin products described herein, the inflated and fraudulent nature of the list price of the insulin products described herein, the relationship between the CVS Health RICO Defendants and their impact upon the price of the insulin products described herein, and the existence, amount, and purpose of rebates and discounts given for the insulin products described herein, and the portion of the rebates and discounts pocketed by CVS Health.

203. The CVS Health RICO Defendants and each member of the conspiracy, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the CVS Health RICO Defendants and their co-conspirators had to agree to conceal their fraudulent negotiations and pricing tactics.

204. The CVS Health RICO Defendants knew, and intended that, Plaintiffs would rely on the material misrepresentations and omissions made by them and incur increased costs as a result. Indeed, if Plaintiffs did not make inflated payments for the insulin products described herein, the CVS Health RICO scheme could not succeed.

205. As described herein, the CVS Health RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs based on their misrepresentations and omissions, while providing insulin products that were worth significantly less than the purchase price paid. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

206. During the CVS Health RICO Defendants' determination of discounts and/or rebates for the insulin products described herein, the true purpose of the discounts, the true cost of the insulin products, and the inflated and fraudulent nature of their pricing was revealed to each of the CVS Health RICO Defendants. Nevertheless, the CVS Health RICO Defendants continued to disseminate misrepresentations regarding the true cost of the insulin products as well as the existence, amount, and purpose of the kickbacks on those products, in furtherance of the scheme.

207. As a result of the conduct of the CVS Health RICO Defendants, and in particular,

their pattern of racketeering activity, Plaintiffs has been injured in its business and/or property in multiple ways, including but not limited to paying excessive and inflated prices for the insulin products described herein.

208. The CVS Health RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs who is entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

COUNT II

VIOLATIONS OF 18 U.S.C. §1962(C)(D) THE RACKETEER INFLUENCED AND **CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961, *ET SEQ.***
(Against Defendants Express Scripts, Sanofi, Novo Nordisk, and Eli Lilly)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

209. Plaintiffs incorporates by reference each preceding paragraph as though fully set forth herein.

210. Plaintiffs brings this Count against Defendants Express Scripts, Sanofi, Novo Nordisk, and Eli Lilly (collectively, for purposes of this Count, the "Express Scripts RICO Defendants").

211. At all relevant times, the Express Scripts RICO Defendants have been "persons" under 18 U.S.C. § 1961(3) because they are capable of holding, and do hold, "a legal or beneficial interest in property."

212. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

213. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

214. As evidenced by Defendant Express Script's formulary placements and exclusions throughout the class period[82] coupled with statements from Manufacturer Defendants stating that PBMs have forced higher rebates to allow Manufacturer Defendants to be placed on CVS Health's formularies.[83]

A. Description of the Express Scripts RICO Enterprise.

215. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). An association-in-fact enterprise requires three structural features: (1) a purpose; (2) relationships among those associated with the enterprise; and (3) longevity sufficient to permit those associates to pursue the enterprise's purpose.

216. For years, Express Scripts and other pharmacy benefits managers played a small but meaningful role in the prescription drug business: providing administrative services on behalf of health plans that offer prescription drug benefits and negotiating with drug manufacturers on their behalf.

217. In the past decade, however, Express Scripts and other PBMs began to exert influence in their role as insurance-industry middle-men to dictate the success or failure of certain drugs in the marketplace by offering to include or threatening to exclude certain medications from some or all of their formularies, and, in the process, extracting hundreds of millions of dollars in the form of 'discounts' or 'rebate' payments, which essentially amounted to illegal kickbacks, from drug manufacturers in exchange.

[82] *See* Composite Exhibit C.
[83] *See* Composite Exhibit B.

218. Negotiations between PBMs and drug manufacturers regarding those discounts, however, take place in complex, closed-door meetings, during which PBMs sell access to their formularies in exchange for large rebates or kickbacks, a substantial portion of which they pocket as pure profit.

219. In order to facilitate the payment of kickbacks to PBMs, and ensure their position on certain formularies without impacting their bottom line, the Drug Manufacturers Defendants participate in a scheme with Express Scripts to increase the list price of their drugs instead of competing on actual price with other insulin manufacturers.

220. This scheme to increase the profits of PBMs through artificially increasing the list price of medications benefits everyone in the prescription drug industry supply chain except Plaintiffs, who is left paying fraudulently obtained, exorbitant, and ever-increasing prices for its medications. The practice is particularly pernicious in the case of medications such as insulin, because it decreases access to life-saving drugs. Nevertheless, insulin medications have become a common target of PBMs, specifically Express Scripts.

221. At all relevant times, the Express Scripts RICO Defendants, along with pharmacies, wholesalers, and other individuals and entities, including unknown third parties, operated an ongoing association-in-fact enterprise. This association-in-fact enterprise was formed for the purpose of ensuring that one or more of Sanofi's, Novo Nordisk's, and Eli Lilly's insulin products were included on Express Scripts' formularies and increasing Express Scripts' profits by fraudulently and artificially increasing the list price of those insulin products at the expense of Plaintiffs, and through which the Express Scripts RICO Defendants conducted a pattern of racketeering activity under 18 U.S.C. § 1961(4).

222. Alternatively, each of the Express Scripts RICO Defendants constitutes a single

legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the Express Scripts RICO Defendants conducted their pattern of racketeering activity. The Express Scripts RICO Defendants' separate legal statuses facilitated the fraudulent scheme and provided a hoped-for shield from liability for the Express Scripts RICO Defendants and their co-conspirators. The enterprises, alleged in this and the previous paragraph, are referred to collectively as the "Express Scripts RICO Enterprise."

223. At all relevant times, the Express Scripts RICO Enterprise constituted a single "enterprise" or multiple enterprises within the meaning of 18 U.S.C. § 1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in Express Scripts RICO Defendants' profit-making scheme.

224. The association-in-fact Express Scripts RICO Enterprise consisted of the following entities and individuals: (a) Express Scripts, its subsidiaries, executives, employees, and agents; (b) Sanofi, its subsidiaries, executives, employees, and agents; (c) Eli Lilly, its subsidiaries, executives, employees, and agents; and (d) Novo Nordisk, its subsidiaries, executives, employees, and agents.

225. While each of the Express Scripts RICO Defendants acquired, maintained control of, were associated with, and conducted or participated in the conduct of the Express Scripts RICO Enterprise's affairs, at all relevant times, the Express Scripts RICO Enterprise: (a) had an existence separate and distinct from each Express Scripts RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the Express Scripts RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Express Scripts RICO Defendants, along with other individuals and entities, including unknown third parties.

226. The Express Scripts RICO Defendants and their co-conspirators, through their illegal Express Scripts RICO Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the Express Scripts RICO Defendants and the other entities and individuals associated-in-fact with the Express Scripts RICO Enterprise's activities by selling insulin products at an inflated and artificial price ("the Express Scripts RICO Scheme").

227. Express Scripts orchestrated the Express Scripts RICO Scheme, whereby Express Scripts, as a PBM, leveraged its dominate position in the prescription drug insurance market to demand that insulin drug manufacturers, like Sanofi, Novo Nordisk, and Eli Lilly, pay substantial kickbacks in order to have their products included or be given priority on Express Scripts' formularies.

228. Insulin manufacturers Sanofi, Novo Nordisk, and Eli Lilly facilitated the Express Scripts RICO Scheme by agreeing to provide ever-larger 'discounts' or 'rebates' to Express Scripts in order to gain or maintain access to its formularies and funding those discounts by artificially increasing the list price of their insulin products.

229. In furtherance of the scheme, the Express Scripts RICO Defendants each affirmatively misrepresented or concealed the existence of the inflated and fraudulent nature of these list price increases as well as the existence, amount, and purpose of the "discounts" given to Express Scripts to Plaintiffs, consumers, health care payers, and the general public. Specifically, the Express Scripts RICO Defendants claimed that the rebates paid to Express Scripts were for the purpose of lowering drug costs when, in fact, they were quid pro quo payments for formulary access that had the opposite effect for Plaintiffs.

B. The Express Scripts RICO Enterprise Sought to Fraudulently Increase Defendants' Profits and Revenues.

230. Each Express Scripts RICO Defendant benefited financially from the Express Scripts RICO Enterprise. Express Scripts received direct rebate, or kickback, payments from Sanofi, Novo Nordisk, and Eli Lilly, which they pocketed as pure profit, as well as other fees.

231. In exchange, one or more of Sanofi's, Novo Nordisk's, and Eli Lilly's products received a favorable position on one, or a number of Express Scripts' formularies, translating into higher sales and profits for each of these manufacturers. And because the Drug Manufacturer Defendants financed the payment of kickbacks by inflating the list prices for those drugs, they maintained and, in some cases, increased their profit margins.

232. At all relevant times, the Express Scripts RICO Enterprise: (a) had an existence separate and distinct from each Express Scripts RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the Express Scripts RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Express Scripts RICO Defendants, along with other individuals and entities, including unknown third parties that operated an association-in-fact enterprise, which was formed for the purpose of ensuring that one or more of Sanofi's, Novo Nordisk's, and Eli Lilly's insulin products were included on Express Scripts' formularies and increasing Express Scripts' profits by fraudulently and artificially increasing the list price of those insulin products at the expense of Plaintiffs, and paying kickbacks from the inflated list price.

233. The Express Scripts RICO Defendants and their co-conspirators, through their illegal Enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to increase revenue for the Express Scripts RICO Defendants and the other entities and individuals associated-in-fact with the Enterprise's activities through the illegal scheme to sell insulin products at an inflated and artificial price. Further, Express Scripts RICO Defendants

committed wire fraud by submitting bills, using interstate wires, for payment that were not in compliance with the AKS and therefore amounted to FCA violations, or Medicare fraud.

234. The Express Scripts RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement, distribution, and sale of insulin products throughout the country, and the receipt of monies from the sale of the same.

235. Within the Express Scripts RICO Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis. The Express Scripts RICO Enterprise used this common communication network for purposes of marketing, pricing, and engaging in negotiations regarding insulin products, their pricing, and placement or position on Express Scripts' formularies and for furthering the Express Scripts RICO Scheme.

236. Each participant in the Express Scripts RICO Enterprise had systematic linkages to each other through corporate ties, contractual relationships, financial ties, and a continuing coordination of activities. Through the Express Scripts RICO Enterprise, the Express Scripts RICO Defendants functioned as a continuing unit with the purpose of furthering the Express Scripts RICO Scheme.

237. The Express Scripts RICO Defendants participated in the operation and management of the Express Scripts RICO Enterprise by directing its affairs, as described herein. While the Express Scripts RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

238. The Express Scripts RICO Defendants exerted substantial control over the Express

Scripts RICO Enterprise, and participated in the affairs of the enterprise by: (a) negotiating and/or offering kickbacks for the insulin products described herein; (b) misrepresenting and/or concealing the existence, amount, or purpose of the kickbacks negotiated for the insulin products described herein; (c) misrepresenting and/or concealing the effect that the negotiated kickbacks had on the price of the insulin products for the end payer; (d) negotiating and/or setting the list price for the insulin products described herein; (e) misrepresenting and/or concealing the true cost of the insulin products described herein; (f) publishing, reproducing, and/or distributing documents containing the list price for the insulin products described herein; (g) negotiating and/or offering preferred formulary placement for the insulin product described herein; (h) misrepresenting and/or concealing the true nature of the relationship and agreements between the members of the enterprise and its effect on the pricing of insulin products; (i) otherwise misrepresenting and/or concealing the inflated and fraudulent nature of the pricing of the insulin products described herein; (j) collecting kickbacks, revenues, and/or profits from the sale of the insulin products described herein; and (k) ensuring that the other Express Scripts RICO Defendants and unnamed co-conspirators complied with and concealed the fraudulent scheme.

239. Without each Express Scripts RICO Defendant's willing participation, the Express Scripts RICO Scheme and common course of conduct would not have been successful.

240. The Express Scripts RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in the Defendants' and others' hands.

C. Predicate Acts: Mail and Wire Fraud.

241. To carry out, or attempt to carry out, the scheme to defraud, the Express Scripts

RICO Defendants, each of whom is a person associated-in-fact with the Express Scripts RICO Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Express Scripts RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

242. Specifically, the Express Scripts RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

243. The multiple acts of racketeering activity which the Express Scripts RICO Defendants committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Express Scripts RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Express Scripts RICO Enterprise. The Express Scripts RICO Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

244. The Express Scripts RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions.

245. In devising and executing the illegal scheme, the Express Scripts RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs or to obtain money from Plaintiffs by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the

Express Scripts RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

246. The Express Scripts RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

(a) Mail Fraud: The Express Scripts RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, price, and/or sell the insulin products described herein by means of false pretenses, misrepresentations, promises, and omissions.

(b) Wire Fraud: The Express Scripts RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

247. The Express Scripts RICO Defendants' use of the mails and wires include, but are not limited to: (a) the transmission of marketing or other materials indicating, setting, or negotiating the price of the insulin products described herein; (b) the transmission of marketing or other materials indicating or advertising that any of the Express Scripts RICO Defendants reduce the price of the insulin products described herein; (c) written, telephone, or electronic communications regarding and/or negotiating the kickback amount of the insulin products described herein; (d) written, telephone, or electronic communications regarding and/or negotiating kickbacks associated for the insulin products described herein; (e) written, telephone, or electronic communications regarding the existence, amount, or purpose of discounts and/or rebates ("kickbacks") for the insulin products described herein; (f) the transmission and/or distribution of the insulin products described herein through the mails; and (g) the use of the mails or wires to bill for or collect kickbacks, revenues, and/or profits from the sale of such insulin products described herein.

248. The Express Scripts RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships, and other third-party entities in furtherance of the scheme.

249. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct designed to increase the cost of insulin medication and fraudulently extract hundreds of millions of dollars of revenue from Plaintiffs.

250. Throughout the class period Express Scripts RICO Defendants submitted numerous bills for insulin in violation of the AKS, thus, constituting violations of the FCA.[84]

251. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiffs has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described above.

252. The Express Scripts RICO Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the Express Scripts RICO Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third- party entities and individuals not named as defendants in this Complaint, have participated as co- conspirators with the Express Scripts RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common

[84] Plaintiff has been assigned over $250 Million in insulin related claims paid amongst all Defendants.

course of conduct.

253. The Express Scripts RICO Defendants aided and abetted others in the violations of the above laws.

254. To achieve their common goals, the Express Scripts RICO Defendants hid from Plaintiffs, insurers, health plans, and the general public the true net price of the insulin products described herein, the inflated and fraudulent nature of the list price of the insulin products described herein, the relationship between the Express Scripts RICO Defendants and their impact upon the price of the insulin products described herein, and the existence, amount, and purpose of rebates and discounts, being essentially kickbacks, given for the insulin products described herein, and the portion of the kickbacks pocketed by Express Scripts.

255. The Express Scripts RICO Defendants and each member of the conspiracy, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the Express Scripts RICO Defendants and their co-conspirators had to agree to conceal their fraudulent negotiations and pricing tactics.

256. The Express Scripts RICO Defendants knew, and intended that, Plaintiffs would rely on the material misrepresentations and omissions made by them and incur increased costs as a result. Indeed, if Plaintiffs did not make inflated payments for the insulin products described herein, the Express Scripts RICO scheme could not succeed.

257. As described herein, the Express Scripts RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs based on their misrepresentations and omissions, while providing insulin products

that were worth significantly less than the purchase price paid. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

258. During the Express Scripts RICO Defendants' determination of discounts and/or rebates for the insulin products described herein, the true purpose of the discounts, the true cost of the insulin products, and the inflated and fraudulent nature of their pricing was revealed to each of the Express Scripts RICO Defendants. Nevertheless, the Express Scripts RICO Defendants continued to disseminate misrepresentations regarding the true cost of the insulin products as well as the existence, amount, and purpose of the kickbacks on those products, in furtherance of the scheme.

259. As a result of the conduct of the Express Scripts RICO Defendants, and in particular, their pattern of racketeering activity, Plaintiffs has been injured in its business and/or property in multiple ways, including but not limited to paying excessive and inflated prices for the insulin products described herein.

260. The Express Scripts RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiffs who is entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

COUNT III

VIOLATIONS OF 18 U.S.C. § 1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961, *ET SEQ.*
(Against Novo Nordisk)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

261. This claim is against Novo Nordisk for actual damages, treble damages, and

equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1962, *et seq.*

262. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

263. Plaintiffs is a "person," as that term is defined in 18 U.S.C. § 1961(3) who was injured in its business or property as a result of Novo Nordisk's wrongful conduct.

264. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

265. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

A. The Levemir/NovoLog Pricing Enterprise.

266. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

267. Novo Nordisk formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Levemir/NovoLog Pricing Enterprise. The Levemir/NovoLog Pricing Enterprise consists of (a) Novo Nordisk, including its employees and agents; (b) the PBM CVS Health, including its employees and agents; and (c) the PBM Express Scripts, including its employees and agents.

268. Alternatively, each of the above-named entities constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the

enterprise conducted a pattern of racketeering activity.

269. The Levemir/NovoLog Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable, formulary position for Novo Nordisk's long-acting analog insulin product, Levemir, and its rapid-acting analog insulin product, NovoLog, as a treatment for type 1 and 2 diabetes to the exclusion or detriment of competitor products and consumers.

270. To accomplish this purpose, the Levemir/NovoLog Pricing Enterprise periodically and systematically inflated the list prices of Levemir and NovoLog and represented—either affirmatively or through half-truths and omissions—to the public, health care payers, and consumers, including Plaintiffs, that Levemir and NovoLog's list prices fairly and accurately reflected the actual cost of this drug. The Enterprise concealed from the public, health care payers, like Plaintiffs, the existence and number of steep rebates, or kickbacks, Novo Nordisk gave to the PBMs. These kickbacks comprised of as much as 45% of the list price. The Levemir/NovoLog Pricing Enterprise also concealed from the public the purpose of these kickbacks. The difference between the list price and the net prices of Levemir and NovoLog negotiated by the PBMs resulted in increased profits for the PBMs, steady profits for the manufacturer and increased costs for Plaintiffs. These large rebates served to ensure that the PBMs would place, and maintain, Levemir and NovoLog in a preferred or favorable position on the PBMs' formularies. By securing a favorable position on the formulary, the Levemir/NovoLog Pricing Enterprise ensured that a larger number of Levemir and NovoLog prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Novo Nordisk and larger spreads for the PBMs.

271. The persons engaged in the Levemir/NovoLog Pricing Enterprise are

systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Novo Nordisk. There is regular communication between Novo Nordisk and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, using the wires and the mail in which Novo Nordisk and the PBMs share information regarding the Levemir and NovoLog list prices and discuss and agree on kickback, or rebate, amounts. Novo Nordisk and the PBMs functioned as a continuing unit for the purposes of implementing the Levemir and NovoLog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

272. At all relevant times, CVS Health was aware of Novo Nordisk's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Health struck kickback deals with Novo Nordisk to conceal the true prices of Levemir and NovoLog and profit from the inflated rebates. CVS Health represented to the public that the rebates it negotiated saved health care payers (including Plaintiffs) money on their prescription needs. But it knew that the rebates did not actually decrease the costs of Levemir and NovoLog for anyone but the PBMs. The published list price was falsely inflated, the PBM Defendants pocketed the rebates, instead of passing the savings. CVS Health also knew, but did not disclose, that other PBMs—Express Scripts—were engaged in the same kickback scheme, to the detriment of the Class. But for the Levemir/NovoLog Pricing Enterprise's unlawful fraud, CVS Health would have had the incentive to disclose the deceit by Novo Nordisk, thereby forcing competition on net price. By failing to disclose this information, CVS Health perpetuated the Levemir/NovoLog Pricing Enterprise's scheme, and reaped substantial profits.

273. At all relevant times, Express Scripts was aware of Novo Nordisk's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express

Scripts struck kickback deals with Novo Nordisk to conceal the true prices of Levemir and NovoLog and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers (including Plaintiffs) money on prescription needs. But it knew that the rebates did not actually decrease the costs of Levemir and NovoLog for consumers. The published list price was falsely inflated, the PBM Defendants pocketed the rebates, instead of passing the savings. Express Scripts also knew, but did not disclose, that other PBMs—CVS Health—were engaged in the same kickback scheme, to the detriment of the Class. But for the Levemir/NovoLog Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Levemir/NovoLog Pricing Enterprise's scheme, and reaped substantial profits due to the active kickback scheme.

274. Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Novo Nordisk's reported list prices, terminate their role in the Levemir/NovoLog Pricing Enterprise, or disclose publicly that the Levemir and NovoLog list prices did not accurately reflect the price actually paid for the drugs.

275. CVS Health, and Express Scripts participated in the conduct of the Levemir/NovoLog Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary positions for Levemir and NovoLog, through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual net prices of Levemir and NovoLog;

b. The extent to which the actual net prices of Levemir and NovoLog departed from the published, artificially-inflated list prices;

c. The extent to which Novo Nordisk and the PBMs had negotiated the rebates discounting the list prices of Levemir and NovoLog in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the general public money;

f. Whether Levemir and NovoLog's "preferred" formulary status reflected the drug's safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees;

g. Whether Levemir and NovoLog would have been placed in a "preferred" formulary position absent the rebates; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Levemir and NovoLog prescriptions.

276. Novo Nordisk alone could not have accomplished the purpose of the Levemir/NovoLog Pricing Enterprise, without the assistance of the PBMs. For Novo Nordisk to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Levemir and NovoLog were given favorable treatment. And the PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the list

prices were artificially inflated. The discounts were fictitious: the result of a deliberate scheme to create large kickbacks without lowering net prices. And, contrary to their representations, the kickbacks benefitted the PBM Defendants by allowing them to pocket the rebates as a kickback. Without these misrepresentations, the Levemir/NovoLog Pricing Enterprise could not have achieved its common purpose.

277. The Levemir/NovoLog Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of individuals throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

278. The impacts of the Levemir/NovoLog Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Levemir and NovoLog list prices and the actual net prices of Levemir and NovoLog is still being maintained, and increased. Consequently, PBMs make a profit on the rebates paid by the Drug Manufacturer Defendants as kickbacks. Under this system, the larger the difference between list and net prices, the greater the spread, *i.e.*, profit, for the PBMs.

279. The foregoing evidenced that Novo Nordisk, CVS Health, and Express Scripts were each willing participants in the Levemir/NovoLog Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Novo Nordisk's artificial inflation of the Levemir and NovoLog list prices, coupled with Novo Nordisk's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payers, like Plaintiffs.

B. Conduct of the Levemir/NovoLog Pricing Enterprise.

280. Novo Nordisk exerted control over the Levemir/NovoLog Pricing Enterprise and participated in the operation or management of the affairs of the Levemir/NovoLog Pricing Enterprise, directly or indirectly, in the following ways:

a. Novo Nordisk selected and published the Levemir and NovoLog list prices;

b. Novo Nordisk periodically raised the published Levemir and NovoLog list prices;

c. Novo Nordisk granted to the PBMs substantial rebates representing discounts off of the Levemir and NovoLog list prices in exchange for the PBMs' promise to give Levemir and NovoLog exclusive or at least favorable, formulary placement;

d. Novo Nordisk concealed from the public the amount and purpose of the rebates, or kickbacks;

e. Novo Nordisk intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Levemir and NovoLog) saved health care payers, like Plaintiffs money on its prescription needs; and

f. Representing to the general public, through stating of Levemir and NovoLog's list prices without stating that the list prices differed substantially from that negotiated by the PBMs, that the Levemir and NovoLog list prices reflected or approximated Levemir and NovoLog's actual costs.

281. The scheme had a hierarchical decision-making structure that was headed by Novo Nordisk. Novo Nordisk controlled the Levemir and NovoLog list prices, and doled out kickbacks to the PBMs in exchange for the PBMs' assurances that Levemir and NovoLog would receive exclusive, or at least favorable, formulary placement.

282. The PBMs also participated in the conduct of the affairs of the Levemir/NovoLog

Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Levemir and NovoLog exclusive or at least favorable formulary placement;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Levemir and NovoLog) saved health care payers, like Plaintiffs, money on its prescription needs; and

c. The PBMs concealed the existence or amount of the rebates—including those given to their competitors—to further the fraudulent pricing scheme, thus allowing PBMs to pocket increased kickbacks.

283. The scheme devised and implemented by Novo Nordisk, as well as other members of the Levemir/NovoLog Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Levemir and NovoLog; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Levemir and NovoLog written by plan members' physicians.

C. Novo Nordisk's Pattern of Racketeering Activity.

284. Novo Nordisk conducted and participated in the conduct of the affairs of the Levemir/NovoLog Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Levemir/NovoLog Pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Levemir and NovoLog pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning

of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Novo Nordisk and the PBMs intended to defraud Plaintiffs, and other intended victims.

285. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Novo Nordisk and the PBMs calculated and intentionally crafted the Levemir and NovoLog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs would be over-billed for Levemir and NovoLog. In designing and implementing the scheme, Novo Nordisk was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting list prices and establishing rebates, not knowing that those rebates were not good faith negotiations, but rather, kickbacks amounting to the AKS.

286. By intentionally and artificially inflating the Levemir and NovoLog list prices, and paying PBMs substantial rebates, knowing that the PBMs pocket substantial spreads as kickbacks for formulary placement, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Novo Nordisk and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

287. Novo Nordisk's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Novo Nordisk was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs. Novo Nordisk has engaged in the

pattern of racketeering activity for conducting the ongoing business affairs of its Levemir/NovoLog Pricing Enterprise.

288. The pattern of racketeering activity alleged herein and the Levemir/NovoLog Pricing Enterprise are separate and distinct from each other. Likewise, Novo Nordisk is distinct from the Levemir/NovoLog Pricing Enterprise.

289. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue unless enjoined by this Court.

D. Novo Nordisk's Use of the U.S. Mail and Interstate Wire Facilities.

290. The Levemir/NovoLog Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Levemir and NovoLog list prices; the payment from Novo Nordisk to the PBMs of substantial kickbacks based off of the list price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the "rebates".

291. The Levemir/NovoLog Pricing Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

292. The nature and pervasiveness of the Levemir and NovoLog pricing fraud scheme, which was orchestrated out of the corporate headquarters of Novo Nordisk and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

293. Many of the precise dates of the Levemir/NovoLog Pricing Enterprise's uses of the

U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Novo Nordisk's, CVS Health's, and Express Scripts' books and records. However, Plaintiffs have knowledge that Defendant's committed wire fraud on September 6, 2011, wherein, Defendant's submitted a bill for payment to Plaintiffs for insulin purchased in Converse, Texas. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, by way of violating the AKS, and how those acts were in furtherance of the scheme; Plaintiffs describes this below. And Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years. These acts were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

294. Novo Nordisk's use of the U.S. Mail and interstate wire facilities to perpetrate the Levemir and NovoLog pricing fraud scheme involved thousands of communications including, *inter alia*:

a. Marketing materials about Novo Nordisk's Levemir and NovoLog products and its price, which Novo Nordisk sent to health care payers and health care providers located across the country;

b. Written communications between Novo Nordisk and the publishers of list price compendia regarding the Levemir and NovoLog list prices and their subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Novo Nordisk and CVS Health

regarding Levemir and NovoLog markups and list prices;

d. Written representations and telephone calls between Novo Nordisk and Express Scripts regarding Levemir and NovoLog markups and list prices;

e. Written representations and telephone calls between Novo Nordisk and CVS Health regarding Levemir and NovoLog rebates;

f. Written representations and telephone calls between Novo Nordisk and Express Scripts regarding Levemir and NovoLog rebates;

g. Hundreds of e-mails between Novo Nordisk and the PBMs agreeing to or effectuating the implementation of the Levemir and NovoLog pricing fraud scheme;

h. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Levemir and NovoLog list prices were; the existence, amount, or purpose of the Levemir and NovoLog rebates; and the true costs of Levemir and NovoLog that were designed to conceal the scheme, deter investigations into Levemir and NovoLog pricing, or forestall changes to healthcare payers' reimbursement of Levemir and NovoLog prescriptions based on something other than Levemir and NovoLog list prices; and

i. receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

295. In addition to the above-referenced RICO predicate acts, it was foreseeable to Novo Nordisk that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payers, like Plaintiffs.

296. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

297. Defendants aided and abetted others in the violations of the above laws.

E. Damages Caused by Novo Nordisk's Levemir and NovoLog Pricing Fraud.

298. Novo Nordisk's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs to be injured in its business or property because Plaintiffs has paid inflated out-of-pocket expenses for Levemir and/or NovoLog.

299. The amount of each of these payments is based on the drug's list price. Therefore, when Novo Nordisk, through the Levemir/NovoLog Pricing Enterprise, artificially inflates the Levemir and NovoLog list prices, it also artificially inflates the consumers' out-of-pocket expenses.

300. Plaintiffs' injuries were proximately caused by Novo Nordisk's racketeering activity. But for the misstatements made by Novo Nordisk and the PBMs and the pricing scheme employed by the Levemir/NovoLog Pricing Enterprise, Plaintiffs would have paid less for Levemir and NovoLog expenses.

301. Plaintiffs' injuries were directly caused by Novo Nordisk's racketeering activity.

302. And although the Levemir/NovoLog Pricing Enterprise was effectuated to give

Novo Nordisk a wrongfully-obtained advantage over its competitors, the harm this suit seeks to remedy was not suffered by Novo Nordisk's competitors.

303. By virtue of these violations of 18 U.S.C. § 1962(c) and (d), Novo Nordisk is liable to Plaintiffs for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT IV
VIOLATIONS OF 18 U.S.C. § 1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961, *ET SEQ.*
(Against Eli Lilly)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

304. This claim is brought against Eli Lilly for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C § 1962, *et seq.*

305. Defendant is a "person" pursuant to 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

306. Plaintiffs is a "person," pursuant to 18 U.S.C. § 1961(3) who was injured in its business or property because of Eli Lilly's wrongful conduct.

307. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

308. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

A. The Humalog Pricing Enterprise.

309. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that,

although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

310. Eli Lilly formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Humalog Pricing Enterprise. The Humalog Pricing Enterprise consists of (a) Eli Lilly, including its employees and agents; (b) the PBM CVS Health, including its employees and agents; and (c) the PBM Express Scripts, including its employees and agents.

311. Alternatively, each of the above-named entities constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity.

312. The Humalog Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable, formulary position for Eli Lilly's long-acting analog insulin product, Humalog, as a treatment for type 1 and 2 diabetes to the exclusion or detriment of competitor products and consumers.

313. To accomplish this purpose, the Humalog Pricing Enterprise periodically and systematically inflated the list price of Humalog and represented—either affirmatively or through half-truths and omissions—to the public, health care payers, including Plaintiffs, and consumers, that Humalog' list price fairly and accurately reflected the actual cost of this drug. The Enterprise concealed from the public, health care payers, like Plaintiffs, the existence and amount of steep rebates Eli Lilly gave to the PBMs. These rebates were worth at least 25% of the list price. The Humalog Pricing Enterprise also concealed from the public the purpose of these rebates, to establish Eli Lilly as a preferred drug. The difference between the list price and the net price of Humalog negotiated by the PBMs resulted in increased profits for the PBMs. These large

kickbacks served to ensure that the PBMs would place, and maintain, Humalog in a preferred or favorable position on the PBMs' formularies. By securing a favorable position on the formulary, the Humalog Pricing Enterprise ensured that a larger number of Humalog prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Eli Lilly and larger spreads for the PBMs.

314. The persons engaged in the Humalog Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Eli Lilly. There is regular communication between Eli Lilly and each of the PBMs in which information is shared. Typically, this communication occurred, and continues to occur, using the wires and the mail in which Eli Lilly and the PBMs share information regarding the Humalog list price and discuss and agree on kickback amounts. Eli Lilly and the PBMs functioned as a continuing unit for the purposes of implementing the Humalog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

315. At all relevant times, CVS Health was aware of Eli Lilly's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Health struck kickback deals with Eli Lilly to conceal the true price of Humalog and profit from the inflated rebates. CVS Health represented to the public that the rebates it negotiated saved health care payers and their plan members money on their prescription needs. But, it knew that the rebates did not actually decrease the cost of Humalog for consumers. The published list price was falsely inflated, the PBM Defendants pocketed the rebates instead of passing the savings on. CVS Health also knew, but did not disclose, that other PBMs—Express Scripts—were engaged in the same rebating scheme, to the detriment of consumers. But for the Humalog Pricing Enterprise's unlawful fraud,

CVS Health would have had the incentive to disclose the deceit by Eli Lilly, thereby forcing competition on net price. By failing to disclose this information, CVS Health perpetuated the Humalog Pricing Enterprise's scheme, and reaped substantial profits.

316. At all relevant times, Express Scripts was aware of Eli Lilly's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express Scripts struck kickback deals with Eli Lilly to conceal the true price of Humalog and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers and their plan members money on their prescription needs. But, it knew that the rebates did not actually decrease the cost of Humalog for consumers. The published list price was falsely inflated, the PBM Defendants pocketed the rebates instead of passing the savings on. Express Scripts also knew, but did not disclose, that other PBMs—CVS Health—were engaged in the same rebating scheme, to the detriment of consumers. But for the Humalog Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Humalog Pricing Enterprise's scheme, and reaped substantial profits.

Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Eli Lilly's reported list prices, terminate their role in the Humalog Pricing Enterprise, nor disclose publicly that the Humalog list price did not accurately reflect the price actually paid for the drug. CVS Health, and Express Scripts participated in the conduct of the Humalog Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary position for Humalog, through a pattern of racketeering activity within the meaning of 18 U.S.C.

§§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual net price of Humalog;

b. The extent to which the actual net price of Humalog departed from the published, artificially-inflated list price;

c. The extent to which Eli Lilly and the PBMs had negotiated the rebates, discounting the list price of Humalog in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the general public money;

f. Whether Humalog's "preferred" formulary status reflected the drug's safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees;

g. Whether Humalog would have been placed in a "preferred" formulary position absent the rebates; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Humalog prescriptions.

317. Eli Lilly alone could not have accomplished the purpose of the Humalog Pricing Enterprise without the assistance of the PBMs. For Eli Lilly to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Humalog was given favorable treatment. And the PBMs did so through misrepresentations: they

told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the list prices were artificially inflated. The discounts were fictitious: the result of a deliberate scheme to create large rebates without lowering net prices, thus allowing PBM Defendants to receive significant kickbacks in violation of the AKS. And, contrary to their representations, the rebates benefitted the PBM Defendants by allowing them to pocket the rebates as a kickback. Without these misrepresentations, the Humalog Pricing Enterprise could not have achieved its common purpose.

318. The Humalog Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of individuals throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

319. The impacts of the Humalog Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Humalog list price and the actual net price of Humalog is still being maintained, and increased. Consequently, PBMs make a profit on the rebates paid by the Drug Manufacturer Defendants. Under this system, the larger the difference between list and net prices, the greater the spread, *i.e.*, profit, for the PBMs.

320. The foregoing evidenced that Eli Lilly, CVS Health, and Express Scripts were each willing participants in the Humalog Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Eli Lilly's artificial inflation of the Humalog list price, coupled with Eli Lilly's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payers, like Plaintiffs.

B. Conduct of the Humalog Pricing Enterprise.

321. Eli Lilly exerted control over the Humalog Pricing Enterprise and participated in the operation or management of the affairs of the Humalog Pricing Enterprise, directly or indirectly, in the following ways:

a. Eli Lilly selected and published the Humalog list price;

b. Eli Lilly periodically raised the published Humalog list price;

c. Eli Lilly granted to the PBMs substantial rebates representing discounts off of the Humalog list price in exchange for the PBMs' promise to give Humalog exclusive, or at least favorable, formulary placement;

d. Eli Lilly concealed from the public the amount and purpose of the kickbacks;

e. Eli Lilly intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that rebates (such as those applied to Humalog) saved health care payers, like Plaintiffs, money on its prescription needs; and

f. Representing to the public, by stating Humalog's list price without stating that the list price differed substantially from that negotiated by PBMs. Humalog list price reflected or approximated Humalog's actual cost.

322. The scheme had a hierarchical decision-making structure that was headed by Eli Lilly. Eli Lilly controlled the Humalog list price, and doled out rebates to the PBMs in exchange for the PBMs' assurances that Humalog would receive exclusive, or at least favorable, formulary placement.

323. The PBMs also participated in the conduct of the affairs of the Humalog Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Humalog's exclusive or at least

favorable formulary placement;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that rebates (such as those applied to Humalog) saved health care payers, like Plaintiffs, money on prescription needs; and

c. The PBMs concealed the existence or amount of the kickbacks—including those given to their competitors—to further the fraudulent pricing scheme.

324. The scheme devised and implemented by Eli Lilly, as well as other members of the Humalog Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Humalog; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Humalog written by plan members' physicians.

C. Eli Lilly's Pattern of Racketeering Activity.

325. Eli Lilly conducted and participated in the conduct of the affairs of the Humalog Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Humalog pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Humalog pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Eli Lilly and the PBMs intended to defraud Plaintiffs, and other intended victims.

326. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Eli Lilly and the PBMs calculated and intentionally crafted the Humalog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs who would be over-billed for Humalog. In designing and implementing the scheme, Eli Lilly was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting list prices and establishing rebates.

327. By intentionally and artificially inflating the Humalog list price, and paying PBMs substantial kickbacks, knowing that the PBMs pocket substantial spreads as kickbacks for formulary placement, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Eli Lilly and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

328. Eli Lilly's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Eli Lilly was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs. Eli Lilly has engaged in the pattern of racketeering activity for conducting the ongoing business affairs of its Humalog Pricing Enterprise.

329. The pattern of racketeering activity alleged herein and the Humalog Pricing Enterprise are separate and distinct from each other. Likewise, Eli Lilly is distinct from the Humalog Pricing Enterprise.

330. The pattern of racketeering activity alleged herein is continuing as of the date of

this complaint, and, upon information and belief, will continue unless enjoined by this Court.

D. Eli Lilly's Use of the U.S. Mail and Interstate Wire Facilities.

331. The Humalog Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Humalog list price; the payment from Eli Lilly to the PBMs of substantial kickbacks based off of the list price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.

332. The Humalog Pricing Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

333. The nature and pervasiveness of the Humalog pricing fraud scheme, which was orchestrated out of the corporate headquarters of Eli Lilly and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

334. Many of the precise dates of the Humalog Pricing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Eli Lilly's, CVS Health's, and Express Scripts' books and records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Scheme; Plaintiffs describes this below. And Defendants have committed,

conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years. These acts were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

335. Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the Humalog pricing fraud scheme involved thousands of communications including, *inter alia*:

a. Marketing materials about Eli Lilly's Humalog product and its price, which Eli Lilly sent to health care payers and health care providers located across the country;

b. Written communications between Eli Lilly and the publishers of list price compendia regarding the Humalog list price and its subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Eli Lilly and CVS Health regarding Humalog markups and list price;

d. Written representations and telephone calls between Eli Lilly and Express Scripts regarding Humalog markups and list price;

e. Written representations and telephone calls between Eli Lilly and OptumRx regarding Humalog markups and list price;

f. Written representations and telephone calls between Eli Lilly and CVS Health regarding Humalog kickbacks;

g. Written representations and telephone calls between Eli Lilly and Express Scripts regarding Humalog kickbacks;

h. Written representations and telephone calls between Eli Lilly and OptumRx regarding Humalog kickbacks;

i. Hundreds of e-mails between Eli Lilly and the PBMs agreeing to or effectuating the implementation of the Humalog pricing fraud scheme;

j. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Humalog list price was; the existence, amount, or purpose of the Humalog rebates; and the true cost of Humalog that were designed to conceal the scheme, deter investigations into Humalog pricing, or forestall changes to healthcare payers' reimbursement of Humalog prescriptions based on something other than Humalog list price; and

k. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

336. In addition to the above-referenced RICO predicate acts, it was foreseeable to Eli Lilly that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payors, like Plaintiffs.

337. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

338. Defendants aided and abetted others in the violations of the above laws.

E. Damages Caused by Eli Lilly's Humalog Pricing Fraud.

339. Eli Lilly's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs to be injured in its business or property because Plaintiffs has paid inflated expenses for Humalog.

340. Plaintiffs' injuries were proximately caused by Eli Lilly's racketeering activity. But for the misstatements made by Eli Lilly and the PBMs, and the pricing scheme employed by the Humalog Pricing Enterprise, Plaintiffs would have paid less for their Humalog expenses.

341. Plaintiffs' injuries were directly caused by Eli Lilly's racketeering activity.

342. And although the Humalog Pricing Enterprise was effectuated to give Eli Lilly a wrongfully-obtained advantage over its competitors, the harm this suit seek to remedy was not suffered by Eli Lilly's competitors.

343. By virtue of these violations of 18 U.S.C. § 1962(c) and (d), Eli Lilly is liable to Plaintiffs for three times the damages Plaintiffs has sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT V
VIOLATIONS OF 18 U.S.C. § 1962(C)-(D) THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961, *ET SEQ.*
(Against Sanofi)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

344. This claim is brought against Sanofi for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C.§ 1962, *et seq.*

345. Defendant is a "person," pursuant to 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

346. Plaintiffs is a "person," pursuant to 18 U.S.C. § 1961(3), who was injured in its

business or property as a result of Sanofi's wrongful conduct.

347. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

348. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

A. The Lantus/Apidra Pricing Enterprise.

349. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

350. Sanofi formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Lantus/Apidra Pricing Enterprise. The Lantus/Apidra Pricing Enterprise consists of (a) Sanofi, including its employees and agents; (b) the PBM CVS Health, including its employees and agents; and (c) the PBM Express Scripts, including its employees and agents.

351. Alternatively, each of the above-named entities constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity.

352. The Lantus/Apidra Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable, formulary position for Sanofi's long-acting analog insulin product, Lantus, and Sanofi's rapid-acting analog insulin, Apidra, as a treatment for type 1 and 2 diabetes to the exclusion or detriment

of competitor products and consumers.

353. To accomplish this purpose, the Lantus/Apidra Pricing Enterprise periodically and systematically inflated the list prices of Lantus and Apidra and represented—either affirmatively or through half-truths and omissions—to the public, health care payers, including Plaintiffs, and consumers, that Lantus' and Apidra's list prices fairly and accurately reflected the actual cost of these drugs. The Lantus/Apidra Pricing Enterprise concealed from the public, health care payers, like Plaintiffs, the existence and amount of steep rebates, or kickbacks, Sanofi gave to the PBMs. These rebates were worth at least 35% of the list price. The Lantus/Apidra Pricing Enterprise also concealed from the public the purpose of these rebates: the difference between the list prices and the net prices of Lantus and Apidra negotiated by the PBMs resulted in increased profits for the PBMs. These large kickbacks served to ensure that the PBMs would place, and maintain, Lantus and Apidra in preferred or favorable positions on the PBMs' formularies. By securing a favorable position on the formulary, the Lantus/Apidra Pricing Enterprise ensured that a larger number of Lantus and Apidra prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Sanofi and larger spreads for the PBMs.

354. The persons engaged in the Lantus/Apidra Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Sanofi. There is regular communication between Sanofi and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, using the wires and the U.S. mail in which Sanofi and the PBMs share information regarding the Lantus and Apidra list prices and discuss and agree on kickback amounts. Sanofi and the PBMs functioned as a continuing unit for the purposes of implementing the Lantus/Apidra pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and

continue its existence.

355. At all relevant times, CVS Health was aware of Sanofi's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Health struck kickback deals with Sanofi to conceal the true prices of Lantus and Apidra and profit from the inflated rebates. CVS Health represented to the public that the rebates it negotiated saved health care payers (including Plaintiffs) and their plan members money on their prescription needs. But, it knew that the rebates did not actually decrease the costs of Lantus and Apidra. The published list price was falsely inflated, the PBM Defendants pocketed the rebates instead of passing the savings on. CVS Health also knew, but did not disclose, that other PBMs—Express Scripts—were engaged in the same kickback scheme, to the detriment of consumers. But for the Lantus/Apidra Pricing Enterprise's unlawful fraud, CVS Health would have had the incentive to disclose the deceit by Sanofi, thereby forcing competition on net price. By failing to disclose this information, CVS Health perpetuated the Lantus/Apidra Pricing Enterprise's scheme, and reaped substantial profits.

356. At all relevant times, Express Scripts was aware of Sanofi's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express Scripts struck kickback deals with Sanofi to conceal the true prices of Lantus and Apidra and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers (including Plaintiffs) and their plan members money on their prescription needs. But, it knew that the rebates did not actually decrease the costs of Lantus and Apidra. The published list price was falsely inflated, the PBM Defendants pocketed the rebates instead of passing the savings on. Express Scripts also knew, but did not disclose, that other PBMs—CVS Health—were engaged in the same kickback scheme, to the detriment of consumers. But for the

Lantus/Apidra Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Lantus/Apidra Pricing Enterprise's scheme, and reaped substantial profits.

357. Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Sanofi's reported list prices, terminate their role in the Lantus/Apidra Pricing Enterprise, nor disclose publicly that the Lantus and Apidra list prices did not accurately reflect the prices actually paid for the drugs.

358. CVS Health, and Express Scripts participated in the conduct of the Lantus/Apidra Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary positions for Lantus and Apidra, through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual net prices of Lantus and Apidra;

b. The extent to which the actual net prices of Lantus and Apidra departed from the published, artificially-inflated list prices;

c. The extent to which Sanofi and the PBMs had negotiated the rebates discounting the list prices of Lantus and Apidra in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the public money;

f. Whether Lantus and Apidra's "preferred" formulary statuses reflected the drugs' safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees, or by illegal kickbacks violating the AKS;

g. Whether Lantus and Apidra would have been placed in "preferred" formulary positions absent the kickbacks; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Lantus and Apidra prescriptions.

359. Sanofi alone could not have accomplished the purpose of the Lantus/Apidra Pricing Enterprise, without the assistance of the PBMs. For Sanofi to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Lantus and Apidra were given favorable treatment. And the PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the list prices were artificially inflated to include room for kickbacks to the PBM. The discounts were fictitious: the result of a deliberate scheme to create large rebates without lowering net prices. And, contrary to their representations, the rebates benefitted the PBM Defendants by allowing them to pocket a significant portion of the rebates as a kickback. Without these misrepresentations, the Lantus/Apidra Pricing Enterprise could not have achieved its common purpose.

360. The Lantus/Apidra Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of individuals throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

361. The impacts of the Lantus/Apidra Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Lantus and Apidra list prices and the net prices of Lantus and Apidra is still being maintained, and increased. Consequently, PBMs and pharmacies make a profit on the rebates paid by the Drug Manufacturer Defendants. Under this system, the larger the difference between list and net prices, the greater the spread, *i.e.*, profit, for the PBMs.

362. The foregoing evidenced that Sanofi, CVS Health, and Express Scripts, were each willing participants in the Lantus/ Apidra Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Sanofi's artificial inflation of the Lantus and Apidra list prices, coupled with Sanofi's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payer, like Plaintiffs.

B. Conduct of the Lantus/Apidra Pricing Enterprise.

363. Sanofi exerted control over the Lantus/Apidra Pricing Enterprise and participated in the operation or management of the affairs of the Lantus/Apidra Pricing Enterprise, directly or indirectly, in the following ways:

a. Sanofi selected and published the Lantus and Apidra list prices;

b. Sanofi periodically raised the published Lantus and Apidra list prices;

c. Sanofi granted to the PBMs substantial rebates representing discounts off of the Lantus and Apidra list prices in exchange for the PBMs' promise to give Lantus and Apidra exclusive or at least favorable, formulary placements;

d. Sanofi concealed from the public the amount and purpose of the rebates;

e. Sanofi intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that

rebates (such as those applied to Lantus and Apidra) saved health care payers, like Plaintiffs, money on its prescription needs; and

f. The public, through stating of Lantus and Apidra's list prices without stating that the list prices differed substantially from that negotiated by PBMs, that the Lantus and Apidra list prices reflected or approximated Lantus and Apidra's actual costs.

364. The scheme had a hierarchical decision-making structure that was headed by Sanofi. Sanofi controlled the Lantus and Apidra list prices, and doled out kickbacks to the PBMs in exchange for the PBMs' assurances that Lantus and Apidra would receive exclusive, or at least favorable, formulary placements.

365. The PBMs also participated in the conduct of the affairs of the Lantus/Apidra Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Lantus and Apidra exclusive or at least favorable formulary placements;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Lantus and Apidra) saved health care payers, like Plaintiffs, money on its prescription needs; and

c. The PBMs concealed the existence or amount of the rebates—including those given to their competitors—to further the fraudulent pricing scheme.

366. The scheme devised and implemented by Sanofi, as well as other members of the Lantus/Apidra Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Lantus and Apidra; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Lantus and Apidra

written by plan members' physicians.

C. Sanofi's Pattern of Racketeering Activity.

367. Sanofi conducted and participated in the conduct of the affairs of the Lantus/Apidra Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Lantus/Apidra Pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Lantus and Apidra pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Sanofi and the PBMs intended to defraud Plaintiffs, and other intended victims.

368. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Sanofi and the PBMs calculated and intentionally crafted the Lantus and Apidra pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs who would be over-billed for Lantus and Apidra. In designing and implementing the scheme, Sanofi was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting list prices and establishing rebates.

369. By intentionally and artificially inflating the Lantus and Apidra list prices, and paying PBMs substantial rebates, knowing that the PBMs pocket substantial spreads as kickbacks for formulary placement, and then subsequently failing to disclose such practices to the individual

patients, health plans, and insurers, Sanofi and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

370. Sanofi's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Sanofi was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs. Sanofi has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Lantus/Apidra Pricing Enterprise.

371. The pattern of racketeering activity alleged herein and the Lantus/Apidra Pricing Enterprise are separate and distinct from each other. Likewise, Sanofi is distinct from the Lantus/Apidra Pricing Enterprise.

372. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

D. Sanofi's Use of the U.S. Mail and Interstate Wire Facilities.

373. The Lantus/Apidra Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Lantus and Apidra list prices; the payment from Sanofi to the PBMs of substantial kickbacks based on the list price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.

374. The Lantus/Apidra Pricing Enterprise's unlawful conduct and wrongful practices

were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

375. The nature and pervasiveness of the Lantus and Apidra pricing fraud scheme, which was orchestrated out of the corporate headquarters of Sanofi and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

376. Many of the precise dates of the Lantus/Apidra Pricing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Sanofi's, CVS Health's, Express and Scripts' books and records. Indeed, an essential part of the successful operation of the Lantus/Apidra Pricing Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme; Plaintiffs describes this below. And Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years. These acts were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

377. Sanofi's use of the U.S. Mail and interstate wire facilities to perpetrate the Lantus and Apidra pricing fraud scheme involved thousands of communications including, *inter alia*:

a. Marketing materials about Sanofi's Lantus and Apidra products and its price, which Sanofi sent to health care payers and health care providers located across the country;

b. Written communications between Sanofi and the publishers of list price compendia regarding the Lantus and Apidra list prices and their subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Sanofi and CVS Health regarding Lantus and Apidra markups and list prices;

d. Written representations and telephone calls between Sanofi and Express Scripts regarding Lantus and Apidra markups and list prices;

e. Written representations and telephone calls between Sanofi and CVS Health regarding Lantus and Apidra kickbacks;

f. Written representations and telephone calls between Sanofi and Express Scripts regarding Lantus and Apidra kickbacks;

g. Hundreds of e-mails between Sanofi and the PBMs agreeing to or effectuating the implementation of the Lantus and Apidra pricing fraud scheme;

h. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Lantus and Apidra list prices were; the existence, amount, or purpose of the Lantus and Apidra rebates; and the true costs of Lantus and Apidra that were designed to conceal the scheme, deter investigations into Lantus and Apidra pricing, or forestall changes to healthcare payers reimbursement of Lantus and Apidra prescriptions based on something other than the Lantus and Apidra list prices; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

378. In addition to the above-referenced RICO predicate acts, it was foreseeable to

Sanofi that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payors, like Plaintiffs.

379. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

380. Defendants aided and abetted others in the violations of the above laws.

E. Damages Caused by Sanofi's Lantus and Apidra Pricing Fraud.

381. Sanofi's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs to be injured in its business or property because Plaintiffs has paid inflated out-of-pocket expenses for Lantus and Apidra.

382. The amount of each of these payments is based on the drug's list price. Therefore, when Sanofi, through the Lantus/Apidra Pricing Enterprise, artificially inflates the Lantus and Apidra list prices, it also artificially inflates the Plaintiffs' expenses.

383. Plaintiffs' injuries were proximately caused by Sanofi's racketeering activity. But for the misstatements made by Sanofi and the PBMs and the pricing scheme employed by the Lantus/Apidra Pricing Enterprise, Plaintiffs would have paid less for Lantus and Apidra expenses.

384. Plaintiffs' injuries were directly caused by Sanofi's racketeering activity.

385. And although the Lantus/Apidra Pricing Enterprise was effectuated to give Sanofi a wrongfully-obtained advantage over its competitors, the harm this suit seek to remedy was not suffered by Sanofi's competitors.

COUNT VI
COMMON LAW FRAUD
(Against All Defendants)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

386. As alleged extensively above, Defendants affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the true cost and/or price of the insulin products described herein; (b) the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the insulin products described herein; (c) the existence, amount, and/or purpose(s) of discounts and/or rebates offered and/or negotiated by Defendants for those products; and (d) the role that Defendants' played in the price paid for the insulin products described herein, including but not limited to marketing material averring that Defendants decrease the price of prescription drugs for consumers.

387. Defendants valued their profits over the trust, health and safety of Plaintiffs' beneficiaries, like S.E., who purchased insulin at the Wal-Mart in Converse, Texas.

388. Necessarily, Defendants took steps to ensure that their employees and co-conspirators did not reveal the details of the Insulin Pricing Scheme to consumers, including Plaintiffs.

389. Defendants' false representations and omissions were material to Plaintiffs.

390. Plaintiffs reasonably relied on Defendants' deception, and Defendants intended that they would so rely. Plaintiffs had no way of discerning that Defendants were, in fact, deceiving them because they possessed exclusive knowledge regarding the nature of insulin pricing;

intentionally concealed the foregoing from, Plaintiffs and the public; and made incomplete or negligent representations about the pricing of the insulin products and the Defendants' role in that pricing, while purposefully withholding material facts from Plaintiffs that contradicted these representations.

391. Defendants' actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health. Indeed, as a direct result of Defendants' actions, access to live-saving insulin medication has been limited, denied, or forgone.

392. Defendants owed Plaintiffs a duty to disclose, truthfully, all the facts concerning the true cost of the insulin products described herein and the inflated and fraudulent nature of their pricing; the existence, amount, and purpose of rebated and discounts negotiated for those products; and the role that Defendants played in increasing the price of the insulin products described herein.

393. Defendants hatched their deceptive schemes and knew that their customers, including Plaintiffs, did not know about (and could not reasonably discover) the manner in which it sought to artificially inflate the price of the insulin medications. Defendants not only concealed all the facts concerning the true cost of the insulin products described herein, but went further to make affirmative misrepresentations in marketing materials and other communications, that Defendants worked to lower the ultimate cost of prescription medications. Defendants engaged in this fraudulent concealment at the expense of Plaintiffs.

394. Plaintiffs was not aware of the concealed and misrepresented material facts referenced above, and they would not have acted as they did, had they known the truth.

395. As a direct and proximate result of Defendants' fraudulent scheme, Plaintiffs sustained damages, including but not limited to paying excessive and inflated prices for the insulin products described herein.

396. Defendants are liable to Plaintiffs for damages in an amount to be proven at trial. Moreover, because Defendants acted wantonly, maliciously, oppressively, recklessly, deliberately, and with intent to defraud Plaintiffs for the purpose of enriching themselves at Plaintiffs' detriment, Defendants' conduct warrants substantial punitive and exemplary damages in an amount to be determined at trial.

COUNT VII
UNJUST ENRICHMENT
(Against All Defendants)

Plaintiffs incorporates by reference paragraphs 1 through 156 as if fully set forth herein.

397. Defendants have benefitted from selling, setting prices for and negotiating discounts for insulin products marketed and sold at an artificially inflated price.

398. Defendants have received and retained unjust benefits from the Plaintiffs, in the form of costs paid, copayments, and coinsurance payments, and inequity has resulted. It is inequitable and unconscionable for Defendants to retain these benefits.

399. Because Defendants concealed their fraud and deception, Plaintiffs was not aware of the true facts concerning the Insulin Pricing Scheme described herein and did not benefit from Defendants' misconduct.

400. Defendants knowingly accepted the unjust benefits of its fraudulent conduct.

401. As a result of Defendants' misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully demands that this Court:

A. Enter judgments against Defendants and in favor of Plaintiffs for violations of the federal

and state laws and legal standards invoked herein;

B. Award preliminary and permanent injunctive and other equitable relief as is necessary to protect the interests of Plaintiffs, including, *inter alia*, an order prohibiting Defendants from engaging in the unlawful acts described above; an order requiring Defendants or their agents to disclose the existence and/or amount of any rebates, discounts, fees, or other payments received by the PBM Defendants for including the prescription insulin medications described herein on any formulary, and an order requiring Defendants or their agents to disclose the true net price of the prescription insulin medication described herein collected by the Drug Manufacturer Defendants;

C. Order Defendants to pay pre-judgment and post-judgment interest as provided for by law or allowed in equity;

D. Award the Plaintiffs damages (i.e., three times overcharges) in an amount to be determined at trial;

E. Award Plaintiffs its costs of suit, including reasonable attorneys' fees as provided by law, including under RICO, the common fund doctrine, and applicable state law;

F. Find that Defendants are jointly and severally liable for all claims;

G. Order that Defendants must notify each individual who paid a copayment or coinsurance for covered prescription drugs that exceeded the true cost of the drug about the pendency of this action so that they may obtain relief from Defendants for their harm; and

H. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiffs demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED on this the 6th day of September, 2017.

Respectfully Submitted,

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